

Virginia Administrative Code

## Chapter 121. Regulated Medical Waste Management Regulations

Part I

Definitions

9VAC20-121-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise. Chapter 14 (§ [10.1-1400](#) et seq.) of Title 10.1 of the Code of Virginia defines words and terms that supplement those in this chapter. The Solid Waste Management Regulations ([9VAC20-81](#)) define additional words and terms that supplement those in the statutes and this chapter. When the statutes, as cited, and the solid waste management regulations, as cited, conflict, the definitions of the statutes are controlling.

"Approved sanitary sewer system" means a network of sewers serving a facility that has been approved in writing by the Virginia Department of Health, including affiliated local health departments. Such sewer systems may be approved septic tank or drainfield systems and onsite treatment systems, or they may be a part of a collection system served by a VPDES permitted treatment works.

"Ash" means the residual waste material produced from an incineration process or any combustion.

"ASTM" means the American Society for Testing and Materials.

"Autoclave" means a wet thermal treatment process that uses saturated steam under a specified amount of pressure for a specified exposure time and at a specific temperature.

"Bioaerosol" means a suspension of airborne particles, generally comprised of microorganisms (e.g., bacteria, viruses) or materials of biological origin released from humans, animals, plants, soil, water, or other sources. Particles range in size from very small to very large, and could include liquid droplets and materials left behind after such droplets evaporate (known as "droplet nuclei").

"Bioburden" means the degree of microbial contamination, including the type and total population of organisms, the number of spore formers present, and their resistance on any material and in a given amount of waste material prior to undergoing treatment.

"Biohazard" means biological substances that pose a threat to the health of living organisms, primarily that of humans, but can include substances harmful to animals.

"Biological indicator" means a preparation of a specific microorganism of a known concentration and resistance to a specific treatment process or to a known physical or chemical condition and is used to evaluate the capability of a process to effectively treat regulated medical waste.

"Biological indicators" include bacterial spores or other microorganisms inoculated onto carriers (such as spore strips), spore suspensions, and self-contained biological indicators.

"Biological toxin" or "toxin" means a poison, especially a protein or conjugated protein produced by certain animals, plants, and pathogenic bacteria that is highly poisonous for other living organisms.

"Biologicals" means any preparations (sera, nonviable vaccines, vaccines attenuated in a manner that prevents propagation, antigens, toxins, and antitoxins) derived from a living organism or its products for use in diagnosis, immunization, or treatment of human beings or animals.

"Blood" means human blood, human blood components (e.g., serum and plasma), and products made from human blood.

"Bloodborne pathogen" means pathogenic microorganisms that are present in human blood (including human blood components and products made from human blood) that can cause disease in humans.

"Board" means the Virginia Waste Management Board.

"Body fluids" means liquid emanating or derived from humans, including blood; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; semen and vaginal secretions; amniotic fluid; and any other body fluids that are contaminated with blood, mixed or combined with body fluids, or suspected by the health care professional in charge of being capable of producing an infectious disease in humans. This term does not include nail and skin clippings, breast milk, sputum, semen, teeth, sweat, tears, urine, vomitus, or saliva that are not contaminated with visible blood unless transmission of an infectious disease is possible as determined by a health care professional.

"Calibration" means the demonstration that a measuring device produces accurate results within specified limits of its operating range.

"Captive regulated medical waste management facility" means a regulated medical waste management facility that is located on property owned or controlled by the generator of all waste managed or disposed of at that facility.

"Category A infectious substance" means an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to the substance occurs. Category A infectious substances are defined by 49 CFR 173.134 of the U.S. Department of Transportation Hazardous Materials Regulations.

"Category A waste" means wastes that are contaminated with a Category A infectious substance and must be packaged and transported in accordance with the U.S. Department of Transportation Hazardous Materials Regulations or an applicable Department of Transportation special permit.

"Challenge testing" means periodic monitoring or testing of a regulated medical waste treatment device or system that employs the use of biological indicators to demonstrate continued, effective operation of the device or system.

"Closure" means the act of securing a regulated medical waste management facility and terminating use of the facility for management of regulated medical waste pursuant to the requirements of this chapter.

"Container" means any portable enclosure in which a material is stored, transported, treated, or otherwise handled.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other body fluids, infectious agent, biohazard, or biological toxin on an item or surface.

"Cremains" means the ash or bone shadows that remain after cremation.

"Culture" means an infectious substance containing a pathogen that is intentionally propagated. "Culture" does not include a human or animal patient specimen.

"Cultures and stock" means materials derived from the management (e.g., the systems used to grow and maintain infectious agents in vitro, including nutrient agars, gels, broths, and cell lines) of agents infectious to humans, and associated biologicals, from medical or pathological laboratories, from research and industrial laboratories, or from the production of biologicals and includes discarded live or attenuated vaccines capable of propagation, or culture dishes and devices used to transfer, inoculate, or mix cultures.

"Cycle" means the total operating time required for a device to treat regulated medical waste, and for an autoclave, includes warm-up, residence time, and cool down time.

"D-value" or "decimal reduction value" means the thermal resistance or time in minutes at a specific temperature that is required for a one-log or 90% reduction of a specific microbial population under specified treatment conditions.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy human pathogens on a surface or item to the point where they are no longer capable of transmitting disease and the surface or item is rendered safe for handling, use, or disposal.

"Department" or "DEQ" means the Virginia Department of Environmental Quality.

"Director" means the Director of the Department of Environmental Quality or the director's designee.

"Discard" means to throw away or reject. When a material is soiled, contaminated, or no longer usable, and it is placed in a waste receptacle for disposal or treatment prior to disposal, it is considered discarded.

"Discharge" or "waste discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of regulated medical waste into or on any land or state waters.

"Disinfectant" means an antimicrobial product used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious agents, such as bacteria, fungi, and viruses, but not necessarily bacterial spores. There are three types of disinfectants registered by EPA based on the type of efficacy data submitted: limited, general or broad-spectrum, and hospital grade.

"Disinfection" means any procedure that involves the application of an antimicrobial agent (disinfectant) registered with EPA that is consistent with its approved use in accordance with the manufacturer's instructions. Disinfection shall not be considered a form of treatment, and appropriate handling of disinfected materials, as well as health and safety precautions, shall still be required to achieve protection of public health and the environment.

"Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste into or on any land or water so that such solid waste or any constituent of it may enter the environment or be emitted into the air or discharged into any waters, including groundwaters.

"Disposal facility" means a facility or part of a facility at which solid waste is intentionally placed into or on any land or water, and at which the solid waste will remain after closure.

"Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

"Efficacy testing" means testing of a treatment method, system, or device, conducted by a laboratory, independent of the system manufacturer, in conformance with generally recognized scientific principles, microbiologic examinations, or other pertinent assessments of waste material to establish operating parameters for effective treatment of regulated medical waste.

"Effluent" means liquid waste such as spills, wash water, and wastewater emanating from regulated medical waste storage, transfer, and treatment areas.

"Empty" means wastes have been removed from a container using the practices commonly employed to remove materials of that type such as pouring, pumping, or aspirating.

"EPA" means the U.S. Environmental Protection Agency.

"Exposure time" or "residence time" means the length of time at which the treatment method is held at a specific temperature, pressure, irradiation level, or chemical concentration for effective treatment of regulated medical waste.

"Federal agency" means any department, agency, or other instrumentality of the federal government, any independent agency, or establishment of the federal government, including any government corporation and the Government Printing Office.

"Generate" means to cause waste to become subject to regulation. At the point a regulated medical waste is discarded, it has been generated. Timeframes associated with storage and refrigeration are linked to the date the waste is placed in storage, not the date the waste is generated.

"Generator" means any person, by site location, whose act or process produces regulated medical waste identified or defined in this chapter or whose act first causes a regulated medical waste to become subject to this chapter.

"Hazardous material" means a substance or material that has been so designated under 49 CFR Parts 171 and 173.

"Hazardous waste" means any solid waste defined as a "hazardous waste" by the Virginia Hazardous Waste Management Regulations.

"Health care professional" means a medical doctor or nurse practicing under a license issued by the Department of Health Professions.

"Household sharps" means any needles, syringes with attached needles, lancets, auto injectors, pen needles, and any other devices that are used to penetrate the skin for the delivery of medications that are derived from households through self-care, rather than under the care of a home health care professional or at a health care facility. "Household sharps" are sharps that, except for the fact that they are derived from a household, would otherwise be classified as a regulated medical waste in accordance with this chapter.

"Household waste" means any waste material, including garbage, trash, and refuse, derived from households. Households include single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas. "Household waste" does not include sanitary waste in septic tanks (septage) that is regulated by other state agencies. Waste generated by a health care professional or nonstationary health care provider administering care in a household, mobile unit, or commercially operated residence, or outpatient recovery facility that meets the definition of regulated medical waste is not household waste and must be managed as regulated medical waste.

"Inactivated" or "inactivation" means having reached the point, through autoclaving, incineration, or other validated treatment process, where the waste material is no longer infectious, does not pose an infection risk, and is not considered to be a regulated medical waste.

"Infectious agent" means any organism or agent, including a synthetic agent, that causes disease or an adverse health impact in humans or can be transferred to humans, as well as animals that have an economic impact on human society.

"Infectious substance" means a material known or reasonably expected to contain a pathogen, including bacteria, viruses, rickettsiae, parasites, fungi, or prions, that can cause disease in humans or animals.

"Inner packaging" means a packaging that is the primary container, such as a red bag or sharps container, for which an outer packaging is required for transport.

"Nonstationary health care provider" means those persons who routinely provide health care at locations that change each day or frequently. This term includes traveling doctors, nurses, midwives, and others providing care in patients' homes, first aid providers operating from emergency vehicles, and mobile blood service collection stations.

"Offsite" means any site that does not meet the definition of onsite, as defined in this part, including areas of a facility that are not on geographically contiguous property or outside of the boundary of the site.

"Onsite" means the same or geographically contiguous property, which may be divided by public or private right-of-way, provided the entrance and exit to the facility are controlled by the owner or the operator of the facility. Noncontiguous properties owned by the same person but connected by a right-of-way that he controls and to which the public does not have access are also considered onsite property.

"Operating parameters" means the specific conditions of pressure, temperature, residence time, chemical concentration, and other physical or engineering condition established through efficacy testing of a treatment method and verified through validation testing to be effective for treatment of regulated medical waste.

"Outer packaging" means packaging that is the secondary container or the outermost enclosure, such as a disposable or reusable rigid pail, fiberboard carton, drum, or portable bin that is under normal conditions of use leak-resistant, strong enough to prevent tearing or bursting, puncture resistant, impervious to moisture, has leak proof sides and bottom, has a tight fitting cover or is otherwise closable, and is in good repair, of a composite or combination packaging together with any absorbent materials, cushioning and any other components necessary to contain and protect inner packaging.

"Overpack" means an enclosure that is used to provide protection or convenience in handling of a package or to consolidate two or more packages. "Overpack" does not include a vehicle, freight container, or aircraft unit load device. Examples of overpacks are one or more packages (i) placed or stacked onto a load board such as a pallet and secured by strapping, shrink wrapping, stretch wrapping, or other suitable means; or (ii) placed in a protective outer packaging such as a box or crate.

"Packaging" means the assembly of one or more containers and any other components necessary to assure compliance with minimum packaging requirements under Regulations Governing the Transportation of Hazardous Materials ([9VAC20-110](#)) or this chapter.

"Parametric controls" or "parametric monitoring device" means real time monitoring instrumentation integral to the treatment unit that is designed to quantitatively measure operational parameters, such as temperature, pressure, or other parameter, and provide an electronic or paper record of measurements that can be correlated to treatment. Parametric controls may be used to regulate or maintain preset operating parameters.

"Pathogen" means a microorganism, including bacteria, viruses, rickettsiae, parasites or fungi, or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals.

"Patient specimen" means human or animal materials collected directly from humans or animals and transported for research, diagnosis, clinical or investigational activities, or disease treatment or prevention. "Patient specimen" includes excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles) until such time that the patient specimen is discarded.

"Prion" means a pathogenic agent that is able to cause abnormal folding of specific normal cellular proteins called "prion proteins," which are found most abundantly in the brain. This abnormal folding is associated with neurological disease. Prions are proteinaceous infectious particles that are highly resistant to all but the most destructive methods of inactivation. They require specific inactivation, disposal, and containment procedures.

"Process rate" means the maximum rate of waste acceptance that a regulated medical waste management facility can process for transfer, treatment, or storage. This rate is limited by the capabilities of equipment, personnel, and infrastructure.

"Processing" means preparation, treatment, or conversion of regulated medical waste by a series of actions, changes, or functions that bring about a decided result.

"Regulated medical waste" or "RMW" means solid wastes defined to be regulated medical wastes in Part II ([9VAC20-121-90](#)) this chapter.

"Regulated medical waste management facility" means a site used for planned transfer, treatment, or disposal of regulated medical waste. A regulated medical waste management facility may consist of more than one transfer, treatment, or disposal unit. A regulated medical waste management facility is a type of solid waste management facility.

"Regulated medical waste transfer station" means a regulated medical waste management facility where regulated medical waste is received for the purpose of its subsequent consolidation, over-packing, storage, trans-loading, or subsequent transfer to another regulated medical waste management facility for further processing, treatment, transfer, or disposal. Parking a vehicle containing regulated medical waste during transportation for 24 hours or more is considered a regulated medical waste transfer station.

"Regulated medical waste treatment facility" means a regulated medical waste management facility where regulated medical waste is treated so that it no longer constitutes a threat to public health and the environment, and the waste is subsequently managed as solid waste.

"Reusable medical device" means a device, including surgical forceps, endoscopes, and stethoscopes, that is designed and labeled for multiple uses and is reprocessed by thorough cleaning followed by high-level disinfection or sterilization between patients.

"Sanitizer" means a substance, or mixture of substances, that reduces the bacterial population in the inanimate environment by significant numbers, (e.g., 3 log<sub>10</sub> reduction) or more but does not destroy or eliminate all bacteria.

"Select agent or toxin" means a subset of biological agents and toxins that the U.S. Department of Health and Human Services and U.S. Department of Agriculture have determined have the potential to pose a severe threat to public health and safety, to animal or plant health, or to

animal or plant products. Select agents and toxins are specified under 42 CFR §§ 73.3 and 73.4, 9 CFR §§ 121.3 and 121.4, and 7 CFR § 331.3.

"Sharps" means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. Sharps include needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Discarded unused sharps contained in the original liner and outer packaging are excluded from this definition.

"Sharps drop box" means a secure, tamper-proof sharps container for the temporary storage of only household sharps provided for the convenience of individual home generators who choose to transport their own household sharps to the collection point and where collected sharps are packaged, labeled, and managed as regulated medical waste.

"Shipment" means the movement or quantity conveyed by a transporter of a regulated medical waste between a generator and a designated facility or a subsequent transporter.

"Shipping paper" means a shipping order, bill of lading, manifest, or other shipping document serving a similar purpose and containing the information required by the U.S. Department of Transportation Hazardous Materials Regulations.

"Site" means all land or water and structures, other appurtenances, and improvements on them used for treating, storing, and disposing of regulated medical waste. This term includes adjacent land within the facility boundary used for the utility systems such as repair, storage, shipping or processing areas, or other areas incident to the management of regulated medical waste.

"Solid waste" means any of those materials defined as "solid waste" in [9VAC20-81-95](#) of the Virginia Solid Waste Management Regulations. Regulated medical waste that has been treated in accordance with this chapter is considered solid waste.

"Spill" means any accidental or unpermitted discharge, leaking, pumping, pouring, emitting, or dumping of wastes or materials that, when spilled, become wastes.

"Spore" means a dormant form of a microorganism that is more resistant to adverse conditions.

"Sterilize" means to inactivate all microorganisms on materials or waste.

"Storage" means the holding, including during transportation, of regulated medical waste.

"Surrogate waste load" means a load of noninfectious material used in validation test runs of treatment units that represents materials and packaging that would be found in the regulated medical waste stream to be treated by the facility.

"Transportation" or "transport" means the movement of regulated medical waste by air, rail, highway, or water.

"Transporter" means a person authorized in accordance with federal and state regulations and engaged in transportation or movement of regulated waste.

"Treatment" means any method, technology, or process designed to change the character or composition of any regulated medical waste so that it is inactivated and no longer constitutes a threat to public health and the environment. Treatment does not include compaction or disinfection.

"Treatment method" means a process including wet thermal sterilization (such as autoclaving) or dry thermal sterilization, chemical sterilization, combustion or incineration, and alternate technologies used to treat regulated medical waste.

"Thermochemical indicator" means a device (e.g., tape, paper strips, integrators, or small ampoules) that responds to the treatment process parameters in some measurable fashion, such as changing color or becoming striped when subjected to temperatures intended to provide sterilization of materials.

"Thermochemical recording device" means a device (e.g., thermocouple, wireless data loggers, or chemical monitoring probes) that reacts in response to one or more critical treatment parameters (such as temperature) and yields a quantifiable value that correlates to microbial lethality or predictable inactivation of microbial spore populations.

"Unauthorized waste" means waste that is not authorized by the department to be managed by the regulated medical waste management facility. Examples are site-specific and dependent upon the treatment technology and permit but may include chemotherapeutic, pathological, pharmaceutical, radioactive, chemical, hazardous, or other wastes.

"Used health care product" means a medical, diagnostic, or research device or piece of equipment, or personal care product used by consumers, medical professionals, or pharmaceutical providers that does not otherwise meet the definition of patient specimen, biological product, or regulated medical waste, but is contaminated with potentially infectious body fluids or materials and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

"Validation testing" means procedures conducted at the site of a regulated medical waste treatment facility prior to initial operation of a treatment system or device, the purpose of which is to demonstrate, through established operating parameters, the effective treatment of regulated medical waste.

"Vector" means a living animal, insect, or other arthropod that is capable of transmitting a pathogen or infectious disease from one organism to another.

"VPDES" means Virginia Pollutant Discharge Elimination System, the Virginia system for the issuance of permits pursuant to the Permit Regulation ([9VAC25-31](#)), the State Water Control Law (§ [62.1-44.2](#) et seq. of the Code of Virginia), and § 402 of the Clean Water Act (33 USC § 1251 et seq.).

"Waste management" means the entire process of managing waste from the point of generation to final disposition. For regulated medical waste, the process includes collection and segregation, characterization, classification, packaging, labeling, processing, staging, storing, decontamination, treatment, transportation, and disposal, as well as monitoring of waste management operations and sites to ensure that the management of these wastes is protective of human health and the environment.

"Waste management facility" means all contiguous land and structures, other appurtenances, and improvements on them used for treating, storing, or disposing of waste.

"Z-value" means the temperature change required for the D-value to change by 1 log (i.e., by a factor of 10) for a specific microbial population under specified treatment conditions.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

#### Part II

##### General Information

##### 9VAC20-121-20. Purpose.

The purpose of this chapter is to establish standards and procedures pertaining to regulated medical waste management in the Commonwealth of Virginia in order to protect the public health and public safety, and to enhance the environment and natural resources.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

##### 9VAC20-121-30. Administration.

A. The Virginia Waste Management Board promulgates and enforces regulations that it deems necessary to protect the public health and safety, the environment, and natural resources.

B. The director is authorized and directed to administer this chapter in accordance with the Virginia Waste Management Act (§§ [10.1-1400](#) through [10.1-1457](#) of the Code of Virginia).

C. Nothing in this chapter shall limit or affect the power of the director, by the director's order, to prohibit storage, transfer, treatment, or disposal of any waste or require special handling requirements the director determines are necessary to protect the public health or the environment.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

##### 9VAC20-121-40. Applicability.

A. This chapter applies (i) to all persons who generate or transport, store, transfer, process, treat, dispose, or otherwise manage regulated medical waste; own or operate a regulated medical waste management facility; or allow a regulated medical waste management facility to be operated on their property in the Commonwealth of Virginia; and (ii) to those who seek approval to engage in these activities, except those specifically exempted or excluded elsewhere in this chapter. A "person" may include an individual, firm, company, corporation, partnership, association, state or federal government and any agency thereof, municipality, commission, political subdivision of a state, or any interstate body.

B. All existing regulated medical waste management facilities must comply with this chapter. Existing facilities, including those with an existing permit, must submit updated permit application documents by September 15, 2024, to come into compliance with this chapter. If the updated application includes changes that result in a different type of facility as outlined in [9VAC20-121-300 C 2](#), a complete permit-by-rule application shall be required. Existing facilities that only make changes to come into compliance with the regulations shall submit the following updated documents, as applicable, in accordance with [9VAC20-121-310](#):

1. DEQ Form RMW PBR;
2. Disclosure statements (DEQ Form DISC-01 and DISC-02), if changes in key personnel;
3. Design and construction certification by a professional engineer, in accordance with [9VAC20-121 310 A 2 c](#);
4. Design plans in accordance with [9VAC20-121-310 A 2 d](#);
5. Facility standards certification and a copy of the Regulated Medical Waste Management Plan in accordance with [9VAC20-121-310 A 2 f](#);
6. Treatment Plan in accordance with [9VAC20-121-310 A 2 h](#) and [i](#), respectively;
7. Closure Plan and closure cost estimate, in accordance with [9VAC20-121-310 A 2 j](#) and [m](#);
8. Certification from the State Corporation Commission, in accordance with [9VAC20-121-310 A 2 l](#), if not previously provided; and
9. Applicable permit fee in accordance with [9VAC20-121-310 A 2 n](#).

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

#### 9VAC20-121-50. Prohibitions.

A. No person shall operate any regulated medical waste management facility for the transfer, treatment, or disposal of regulated medical waste without a permit from the director.

B. No person shall allow regulated medical waste to be stored, disposed, or otherwise managed on the person's property except in accordance with this chapter.

C. It shall be the duty of all persons to manage their regulated medical waste in a legal manner. Untreated regulated medical waste, including its packaging, shall not be used, reused, or reclaimed.

D. No person shall:

1. Allow regulated medical waste to drain or discharge into surface waters except when treated onsite and discharged into surface water as authorized under a Virginia Pollutant Discharge Elimination System (VPDES) Permit ([9VAC25-31](#)).
2. Cause the discharge of pollutants into waters of the United States, including wetlands, that violates any requirements of the Clean Water Act (33 USC § 1251 et seq.), including the VPDES requirements and Virginia Water Quality Standards ([9VAC25-260](#)).
3. Cause the discharge of a nonpoint source of pollution to waters of the United States, including wetlands, that violates any requirement of an area wide or statewide water quality management plan that has been approved under § 208 or 319 of the Clean Water Act (33 USC § 1251 et seq.) or violates any requirement of the Virginia Water Quality Standards ([9VAC25-260](#)).
4. Allow regulated medical waste to be deposited in or to enter any surface waters, groundwaters, or storm drains.

E. Any person who violates subsection A, B, C, or D of this section shall immediately cease the activity of improper management and shall initiate waste removal, cleanup, or closure.

## Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-60. Enforcement and appeal.

A. All administrative enforcement and appeals taken from actions of the director relative to the provisions of this chapter shall be governed by the Virginia Administrative Process Act (§ [2.2-4000](#) et seq. of the Code of Virginia).

B. The Virginia Waste Management Board or the director may enforce the provisions of this chapter utilizing all applicable procedures under the law. The powers of the board and the director include those established under Chapter 11.1 (§ [10.1-1182](#) et seq. of the Code of Virginia); in Article 8 (§ [10.1-1455](#) et seq.) of Chapter 14 of Title 10.1 of the Code of Virginia; and particularly in § [10.1-1186](#) of the Code of Virginia. These sections describe the right of entry for inspections; the issuance of orders, penalties, injunctions; and other provisions and procedures for enforcement of this chapter.

## Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-70. Public participation and information.

A. All permits for regulated medical waste management facilities are subject to public participation, as specified in Part V ([9VAC20-121-300](#) et seq.) of this chapter.

B. Modifications to regulated medical waste management facility permits shall be subject to public participation in accordance with Part V ([9VAC20-121-300](#) et seq.) of this chapter.

C. Dockets of all permitting actions, enforcement actions, and administrative actions relative to this chapter shall be available to the public for review, consistent with the Virginia Administrative Process Act, Virginia Freedom of Information Act (§ [2.2-3700](#) of the Code of Virginia), and the provisions of this chapter.

D. Public participation in the compliance evaluation and enforcement programs is encouraged. The department will:

1. Investigate all citizen complaints and provide written responses to all signed, written complaints from citizens, concerning matters within the board's purview;
2. Not oppose intervention by any citizen in a suit brought before a court by the department as a result of the enforcement action; and
3. Provide notice on the department's website and provide at least 30 days of public comment on proposed settlements of civil enforcement actions, except where the settlement requires some immediate action. Where a public comment period is not held prior to the settlement of an enforcement action, public notice will still be provided following the settlement.

## Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-80. Relationship to other bodies of regulation.

A. The Solid Waste Management Regulations ([9VAC20-81](#)) address other requirements for solid waste management. If there is a conflict between the provisions of this chapter and the solid waste management regulations, this chapter is controlling.

B. Regulated medical waste management facilities must also comply with any applicable sections of the Hazardous Waste Management Regulations ([9VAC20-60](#)). If there is a conflict between the provisions of this chapter and the hazardous waste management regulations, [9VAC20-60](#) is controlling.

C. Intrastate shipment of hazardous materials is subject to the Regulations Governing the Transportation of Hazardous Materials ([9VAC20-110](#)). If there is a conflict between the provisions of this chapter and the hazardous materials transportation regulations, [9VAC20-110](#) is controlling.

D. Generators of regulated medical waste and regulated medical waste management facilities may be subject to the general industry standard for occupational exposure to bloodborne pathogens in [16VAC25-90-1910.1030](#) (29 CFR 1910.1030).

E. Persons transporting regulated medical waste are subject to the federal requirements in the U.S. Department of Transportation Hazardous Material Regulations at 49 CFR Parts 171 through 180.

F. Facilities managing select agents or toxins are subject to the Regulations for Disease Reporting and Control ([12VAC5-90](#)) as administered by the Virginia Department of Health. Facilities that possess, use, or transfer select agents or toxins are also subject to registration, reporting, inactivation, destruction, and compliance with the U.S. Department of Health and Human Services and U.S. Department of Agriculture's Federal Select Agent Program and the federal select agent regulations at 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

G. If there is a conflict between provisions of this chapter and adopted regulations of another agency of the Commonwealth, the provisions of these regulations are set aside to the extent necessary to allow compliance with the regulations of the other agency. If neither regulation controls, the more stringent standard applies.

H. Nothing in this chapter either precludes or enables a local governing body to adopt ordinances. Compliance with one body of regulation does not ensure compliance with the other, and normally, both bodies of regulation must be fully complied with.

I. The Financial Assurance Regulations for Solid Waste Disposal, Transfer, and Treatment Facilities ([9VAC20-70](#)) shall be applicable in all parts to regulated medical waste management facilities. Nothing in this chapter governing regulated medical waste management shall be considered to delete or alter any requirements of the department as set out in Financial Assurance Regulations for Solid Waste Facilities.

J. The U.S. Nuclear Regulatory Commission, 10 CFR, regulates management of radioactive materials. The Virginia Department of Health has established other requirements in accordance with Title 32.1 of the Code of Virginia. No regulated medical waste containing radioactive materials, regardless of amount or origin, shall be treated unless its management and treatment are in full compliance with these two bodies of regulations and are deemed by both regulations to represent no threat to public health and the environment.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-90. Identification of regulated medical waste.

A. A solid waste is a regulated medical waste subject to this chapter if it meets the criteria under subsection B of this section, unless specifically excluded or exempted by subsection C or D of this section. Claims that materials are not regulated medical wastes or are conditionally exempt from regulation shall demonstrate that the material meets the terms of an exemption. In doing so, appropriate documentation shall be provided to demonstrate that the material is not a regulated medical waste or is exempt from regulation.

B. A solid waste is a regulated medical waste if it meets either of the two criteria of this subsection:

1. The solid waste is suspected by the health care professional in charge of being capable of producing an infectious disease in humans. A solid waste shall be considered to be capable of producing an infectious disease if it has been or is likely to have been contaminated by an organism likely to be pathogenic to healthy humans, such organism is not routinely and freely available in the community, and if such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease. If the exact cause of a patient's illness is unknown, but the health care professional in charge suspects a contagious disease is the cause, the likelihood of pathogen transmission shall be assessed based on the pathogen suspected of being the cause of the illness.

2. The solid waste or solid waste stream is identified in the following list:

a. Discarded cultures, stocks, specimens, vaccines, and associated items likely to have been contaminated by them are regulated medical wastes if they are likely to contain organisms likely to be pathogenic to healthy humans. Wastes from the production of biologicals and antibiotics likely to have been contaminated by organisms likely to be pathogenic to healthy humans are regulated medical wastes;

b. Wastes consisting of human blood or body fluids, containers of human blood or body fluids, and items contaminated with human blood or body fluids are regulated medical waste. Human blood and body fluids solidified by absorbent gel, powder, or similar means are also regulated medical waste.

c. Human pathological and anatomical waste, including tissues, organs, body parts, and other pathological or anatomical wastes;

- d. Sharps likely to be contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. This also includes sharps generated through veterinary practice, acupuncture needles, and household sharps collected in a sharps drop box;
- e. When animals are intentionally infected with organisms likely to be pathogenic to healthy humans for the purposes of research, in vivo testing, production of biological materials, or any other reason, the animal carcasses, body parts, bedding material, and all other wastes likely to have been contaminated are regulated medical wastes when discarded, disposed of, or placed in storage;

f. Wastes that are contaminated with a Category A infectious substance are regulated medical waste that shall be managed in accordance with [9VAC20-121-160](#);

g. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any regulated medical waste; and

h. Any solid waste contaminated by or mixed with regulated medical waste, including solid wastes that are packaged as regulated medical wastes.

C. The following materials are not solid wastes or regulated medical wastes:

1. Domestic sewage, including wastes that are not stored and are disposed of in a sanitary sewer system (with or without grinding).
2. Any mixture of domestic sewage and other wastes that pass through a sewer system to a wastewater treatment works permitted by the State Water Control Board or the Virginia Department of Health.
3. Sanitary waste from septic tanks (septage) and sewage holding tanks that is regulated by other state agencies.
4. Human remains when:
  - a. Under the control of a licensed physician or dentist, when the remains are being used or examined for medical purposes and are not solid wastes;
  - b. Provided to qualified educational programs as anatomical gifts;
  - c. Removed during a medical procedure and retained by the patient for religious or other purposes provided that the remains are not a source of disease transmission, as determined by a health care professional; or
  - d. Properly interred in a cemetery or in preparation by a licensed funeral director or embalmer for such interment or cremation.
5. Individual human and animal cremains.
6. Dead or diseased animals subject to regulation by the Virginia Department of Agriculture and Consumer Services.
7. Bed linen, instruments, medical care equipment, and other materials that are routinely cleaned and reused for their original purpose are not subject to this chapter until they are discarded and are a solid waste unless a health care professional has determined these items to be capable of producing an infectious disease in humans in accordance with subdivision B 1 of this section. These items do not include reusable carts or containers used in the management of regulated medical waste, which shall be managed in accordance with [9VAC20-121-130](#).
8. Used health care products and reusable medical devices, being returned to a manufacturer or third party for reprocessing (cleaning and disinfecting or sterilizing) and reuse if packaged and labeled in accordance with 49 CFR 173.134(b)(12)(ii)(A) through (D) and reprocessed in accordance with applicable U.S. Food and Drug Administration requirements. Used health care products and contaminated medical devices or equipment that meet either of the two criteria in subsection B of this section being sent offsite for recycling or disposal are regulated medical waste and shall be managed in accordance with this chapter. These items do not include reusable carts or containers used in the management of regulated medical waste, which shall be managed in accordance with [9VAC20-121-130](#).
9. The following items while in use: samples for laboratory tests, patient specimens, and criminal evidence items taken during enforcement procedures that meet the definition of regulated medical waste. Once these items are no longer needed for their intended purpose, they shall be managed as regulated medical waste unless exempt under subsection D of this section.
10. Tissue blocks of organs or tissues (except those associated with prions) that have been fixed in paraffin or similar embedding materials for cytological or histological examinations. Once these items are no longer needed for their intended purpose, they may be managed as solid waste.

D. The following solid wastes are not regulated medical wastes for purpose of this chapter:

1. Wastes that have been treated in accordance with this chapter are no longer regulated medical waste and may be used, reused, or reclaimed in accordance with the provisions of the Virginia Solid Waste Management Regulations ([9VAC20-81](#)), provided the following requirements are met:

- a. Treated waste that was once regulated but is no longer regulated medical waste shall not be repackaged as regulated medical waste. Solid waste repackaged as regulated medical waste is regulated medical waste.
  - b. If the solid waste is no longer regulated medical waste because of treatment, the generator and the permitted treatment facility shall maintain a record of the treatment for three years after treatment. Generators treating regulated medical waste onsite shall maintain records in accordance with applicable provisions of Part V ([9VAC20-121-300](#) et seq.) of this chapter. Generators shipping regulated medical waste offsite for treatment shall maintain records in accordance with [9VAC20-121-100 I](#).
  - c. The generator or proposed user of treated regulated medical waste may request that the department make a case-specific determination that the solid waste may be beneficially used in a manufacturing process to make a product or as an effective substitute for a commercial product. The requestor shall submit a beneficial use demonstration in accordance with the requirements of [9VAC20-81-97](#).
2. Household waste, including household sharps. Household sharps shall be placed in an opaque, leak proof, puncture resistant container that is closed, tightly sealed, and labeled for home use before being mixed with other solid wastes or disposed. Household sharps may be placed in U.S. Food and Drug Administration-cleared sharps containers if specifically designed and labeled for home use. Household sharps containers shall be labeled "HOUSEHOLD SHARPS – DO NOT RECYCLE" or "HOME GENERATED SHARPS – DO NOT RECYCLE" printed in large legible text and permanent ink. Household sharps centrally collected in a sharps drop box shall be managed as regulated medical waste in accordance with [9VAC20-121-300 E 1](#). Medical waste generated by a health care professional administering care in a household is regulated medical waste and must be managed in accordance with this chapter.
  3. Nail and skin clippings, breast milk, sputum, semen, teeth, sweat, tears, urine, vomitus, or saliva, unless contaminated with visible blood or a health care professional has determined these items to be capable of producing an infectious disease in humans in accordance with subdivision B 1 of this section.
  4. Dental amalgam managed in accordance with the Dental Rule (40 CFR Part 441).
  5. Meat or other food items being discarded because of spoilage, contamination, or recall.
  6. The following discarded items, when they are unused or expired: health care products, medical equipment, medical devices, unused sharps in the original packaging, or other materials, unless a health care professional has determined these items to be capable of producing an infectious disease in humans in accordance with subdivision B 1 of this section.
  7. Used products for personal hygiene, such as diapers, facial tissues, underpads, adult incontinence products, sanitary napkins, and feminine hygiene items, unless a health care professional has determined these items to be capable of producing an infectious disease in humans in accordance with subdivision B 1 of this section.
  8. The following discarded items when they are empty: urine collection bags and tubing, suction canisters and tubing, IV solution bags and tubing, colostomy bags, ileostomy bags, urostomy bags, plastic fluid containers, enteral feeding containers and tubing, hemovacs, urine bottles, and urine specimen cups, unless the items are subject to regulation under [16VAC25-90-1910.1030](#) (29 CFR 1910.1030) or a comparable state or federal standard.
  9. The following discarded items: urinary catheters, suction catheters, plastic cannula, IV spikes, nasogastric tubes, oxygen tubing and cannula, ventilator tubing, enema bags and tubing, enema bottles, thermometer probe covers, irrigating feeding syringes, and bedpans or urinals, unless the items are subject to [16VAC25-90-1910.1030](#) (29 CFR 1910.1030) or a comparable state or federal standard.
  10. Items such as bandages, gauze, or cotton swabs or other similar absorbent materials, unless at any time following use the items are saturated or would release human blood or human body fluids in a liquid or semiliquid state if compressed. Items that contain or that are caked with dried human blood or human body fluids and are capable of releasing these materials during handling are regulated medical waste. An item would be considered caked if it could release flakes or particles when handled.
  11. Human blood and body fluids when solidified by absorbent gel, powder, or similar means as part of a spill cleanup at establishments engaged in operations other than health care or management of regulated medical waste. This category includes waste generated by stores, markets, office buildings, restaurants, businesses, schools, manufacturers, and commercial or industrial operations.
  12. Waste generated from the care of an animal when care is provided by the owner of the animal, such as at a household or farm. Waste generated through veterinary practice that meets either of the two criteria of subsection B of this section, such as sharps, must be managed as regulated medical waste.
  13. Waste from cosmetology, ear and body piercing, nail salons, and tattoo establishments, except for sharps and unabsorbed human blood or body fluids.
  14. Plant or animal wastes, such as bat guano, removed from construction or demolition projects when actions are taken to avoid worker exposure, including use of appropriate personal protective equipment, and the waste is managed in accordance with any applicable best management practice, special handling, and other precautions for processing or disposal.

15. Waste from food, drug, and cosmetics testing laboratories (except research laboratories) using microbiological methods for the detection of human infectious agents, microbial toxins, or chemical residuals as part of routine quality assurance testing of food, drugs, or cosmetic products.

16. Wastes regulated by the Virginia Department of Health, the State Water Control Board, the Air Pollution Control Board, Department of Agriculture and Consumer Services, Federal Drug Administration, U.S. Department of Agriculture, or any other state or federal agency with such authority.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

Part III

Standards for Management of All Regulated Medical Waste

9VAC20-121-100. General handling and generator requirements.

A. Any person or facility handling, generating, storing, transporting, transferring, treating, or disposing of regulated medical waste shall comply with the general management requirements of this section.

B. All generators must identify and segregate regulated medical waste from other waste, including radioactive waste, hazardous waste, and other solid waste, at the point of origin or as soon as practicable after generation. When practical, the generator shall segregate regulated medical waste based on the anticipated treatment method.

C. All generators must comply with the packaging, labeling, storage, reusable container, spill cleanup, transportation, and Category A waste management requirements for regulated medical waste outlined in Part III ([9VAC20-121-100](#) et seq.) of this chapter, as applicable.

D. Anyone handling or packaging regulated medical waste and loading, unloading, or handling containers of regulated medical waste shall wear appropriate personal protective equipment in accordance with the standards for occupational exposure to bloodborne pathogens in the general industry standard in [16VAC25-90-1910.1030](#) (29 CFR 1910.1030).

E. All regulated medical waste shall be handled in a manner that maintains the integrity of the packaging at all times, prevents damage, leakage, and spills and provides protection from the elements, vectors, and trespassers.

F. Trash chutes shall not be used to manage regulated medical waste. If slides, cart tippers, conveyors, or similar equipment are used to move regulated medical waste from the point of generation to storage areas, between containers, or to vehicles or treatment devices, the movement and impact shall be controlled to maintain the integrity of the regulated medical waste packaging and prevent damage, leaks, and spills. Waste shall not be thrown, dumped, walked upon, or handled in any other manner that could result in spills or releases of regulated medical waste or damage to the packaging.

G. Except in accordance with [9VAC20-121-240 B](#), regulated medical waste shall not be manually or mechanically compacted, compressed, or subjected to violent mechanical stress prior to treatment; however, after regulated medical waste is fully treated and is no longer regulated medical waste, it may be compacted in a closed container in a safe and sanitary manner.

H. All regulated medical waste generated shall either be treated onsite in accordance with Part IV ([9VAC20-121-200](#) et seq.) of this chapter or packaged, labeled, and transported offsite to a facility permitted to receive the waste for transfer, treatment, or disposal.

I. Generators of regulated medical waste are subject to the following recordkeeping requirements:

a. The generator shall maintain all records of onsite treatment or shipment offsite for a minimum of three years following treatment or shipment. All records shall be available for review by the department upon request.

b. Generators treating regulated medical waste onsite, regulated medical waste transfer stations, and all other regulated medical waste treatment or disposal facilities shall maintain records in accordance with applicable provisions of Part V ([9VAC20-121-300](#) et seq.) of this chapter.

c. Generators shipping regulated medical waste offsite for transfer, treatment, or disposal shall maintain records, including copies of all shipping papers, specifying the date of shipment, amount of waste removed from the site, and the names, addresses, and telephone numbers of the transporter and the destination facility receiving the shipment for treatment or disposal.

d. If regulated medical waste is received from offsite, records shall be maintained for three years following receipt of the waste and shall include the date of receipt, name of each offsite generator (except for generators of household sharps using sharps drop boxes), amount of

waste received, and dates of subsequent treatment or shipment offsite.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-110. Packaging and labeling of regulated medical waste.

- A. All regulated medical waste shall be appropriately packaged, labeled, and managed as required by this section.
- B. The generator of regulated medical waste is responsible for the packaging and labeling of regulated medical waste. Contractors or other agents may provide services to the generator, including packaging and labeling of regulated medical waste; however, no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the regulated medical waste as required by this chapter.
- C. No person shall receive for transportation, transfer, storage, or treatment any regulated medical waste that is not packaged and labeled in accordance with this chapter. Contractors or other agents may package or label regulated medical wastes to comply with this chapter, so long as the packaging and labeling is performed onsite where the regulated medical waste was generated and no transportation, storage, treatment, or disposal occurs prior to the packaging. Nothing in this section shall prevent the proper repackaging and further transportation of regulated medical waste that has spilled during transportation.
- D. All regulated medical waste shall be packaged and labeled onsite prior to storage, treatment, transport, or other management and at a minimum must conform with the following:
1. When regulated medical wastes are first discarded, they shall be placed directly in bags or containers meeting the requirements of the standards for occupational exposure to bloodborne pathogens in the general industry standard in [16VAC25-90-1910.1030](#) (29 CFR 1910.1030). The general industry standard requires the packaging to be closable, constructed to contain all contents and prevent leakage of fluids, labeled, and closed prior to removal. Red bags shall be used for the packaging of all regulated medical waste except as provided in subdivision 2 of this subsection.
  2. Sharps shall be placed directly in puncture resistant containers as required by the general industry standards in [16VAC25-90-1910.1030\(d\)\(4\)\(iii\)\(A\)](#). Sharps containers must not be filled beyond the fill line indicated on the container.
  3. Waste packages must not be overfilled. As a bag or container becomes full at the point of generation, and prior to moving, it shall be closed, capped, or sealed so that no waste materials can leak, spill, or protrude during handling, storage, or transport.
  4. Once closed, capped, and sealed, bags and containers of regulated medical waste shall not be opened, unsealed, unpackaged, or repackaged. If damage, spills, or outside contamination of the regulated medical waste packaging occurs, the bag or container shall be placed in a secondary packaging that meets all requirements of this subsection.
  5. All regulated medical waste packaging shall be labeled. The label shall be securely attached to or printed on packaging. The label may be a tag or sticker securely affixed to the package. Permanent ink shall be used to complete the information on the label. The label and the information provided on the label must be clearly legible. The following information shall be included:
    - a. The name, address, and business telephone number of the generator. For hospitals, the label shall identify the specific department or lab where the waste originated;
    - b. The words "Regulated Medical Waste," "Biohazard," or "Infectious Waste" in large print; and
    - c. The universal biohazard symbol.



E. When regulated medical waste is conveyed in reusable carts or containers, the waste in the cart or container shall be packaged and labeled in accordance with this section.

F. When not being filled and prior to moving, wheeled carts and other items used to move regulated medical waste shall be secured, locked, or sealed so that no waste materials can leak and labeled with the universal biohazard symbol or color-coded red to indicate that the contents contain regulated medical waste.

G. Wheeled carts and roll-off containers shall not be used for the holding of liquids, sharps, animal carcasses or body parts, and human anatomical waste, including tissues, organs, or body parts, unless the regulated medical waste is:

1. Properly contained in rigid containers capable of retaining liquids with enough absorbent material to absorb all liquid present, and
2. Separated from other types of regulated medical waste by a leak-proof rigid barrier, divider, or separate compartment.

H. Prior to transporting regulated medical waste offsite for treatment, transfer, or disposal, waste shall be packaged and labeled for transportation in accordance with the standards of 49 CFR Part 173 of the U.S. Department of Transportation Hazardous Materials Regulations or packaged in accordance with an exemption approved by the U.S. Department of Transportation.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-120. Storage of regulated medical waste.

A. The requirements of this section apply to storage of regulated medical waste, including storage (i) in soiled utility rooms and other accumulation areas; (ii) at a generating facility; (iii) during transportation; (iv) at a regulated medical waste transfer stations; and (v) at a regulated medical waste treatment or disposal facility. This section also applies to areas used to transfer a load of regulated medical waste from one vehicle to another or when a vehicle containing regulated medical waste is parked for 24 hours or more during transportation.

B. All regulated medical waste shall be stored in a manner that:

1. Maintains the integrity of the packaging at all times, prevents damage, leakage, and spills and provides protection from the elements, vectors, and trespassers;
2. Maintains the packaging in an upright and stable configuration to minimize the potential for spills. If packages or containers are stacked, except during transport, the top of the stacked containers must not be more than six feet above the level of the floor. The integrity of the containers must not be compromised by the stacking arrangement;
3. Is clean and orderly and located in areas free of standing liquid and debris;
4. Provides security from unauthorized access and protects workers and the general public. Regulated medical waste shall be stored in areas where access is limited to only those persons specifically designated to manage regulated medical waste;
5. Meets the packaging and labeling requirements of [9VAC20-121-110](#); and
6. Meets the requirements of [9VAC20-121-130](#) when regulated medical waste is stored in reusable carts or containers.

C. Regulated medical waste transfer stations, treatment facilities, and generators of 250 gallons or more of regulated medical waste per calendar month are subject to the following storage requirements:

1. All regulated medical waste shall be stored on surfaces that are cleanable and impermeable to liquids. Carpets and floor coverings with cracks or gaps shall not be used in storage areas. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement.
2. In areas used to store regulated medical waste, all floor drains shall discharge directly to an approved sanitary sewer system, and all ventilation shall discharge so as to minimize human exposure to the waste.
3. Signage shall be displayed to indicate any areas used to store regulated medical waste.

D. All regulated medical waste shall be stored in accordance with the following timeframes:

1. Generators of less than 250 gallons of regulated medical waste per calendar month shall arrange for the removal of all regulated medical waste stored onsite at least once per calendar month and provide shipment to a facility permitted to receive it for transfer, treatment, or disposal. No regulated medical waste shall be stored onsite for more than 45 calendar days, and no more than 250 gallons of regulated medical waste shall be stored onsite at any given time. Records shall be maintained in accordance with [9VAC20-121-100 I](#).

2. Generators of 250 gallons or more of regulated medical waste per calendar month shall arrange for the removal of all regulated medical waste stored onsite at least once per calendar week and provide shipment to a facility permitted to receive it for transfer, treatment, or disposal. No regulated medical waste shall be stored onsite for more than 10 calendar days. Records shall be maintained in accordance with [9VAC20-121-100 I](#).

3. Regulated medical waste treatment facilities shall provide treatment or removal of all regulated medical waste stored onsite on at least a weekly basis. No regulated medical waste shall be stored onsite for more than 10 calendar days. Records shall be maintained in accordance with [9VAC20-121-340](#), as applicable.

4. Regulated medical waste transfer stations shall store unrefrigerated regulated medical waste onsite for no more than seven calendar days. All regulated medical waste stored for more than seven calendar days must be refrigerated and stored in an ambient temperature between 35°F and 45°F (2°C and 7°C). No regulated medical waste shall be stored onsite for more than a total of 15 calendar days. Records shall be maintained in accordance with [9VAC20-121-340](#), as applicable.

5. Regulated medical waste transfer stations and treatment facilities shall clearly demonstrate the length of time that regulated medical waste is accumulated onsite by marking the outer packaging in permanent ink or maintaining an inventory, barcode, log, or other recordkeeping system.

E. Except in accordance with a permit:

1. No more than 25% of the regulated medical waste stored onsite each month shall be generated or received from offsite, except for emergency cleanups conducted in accordance with [9VAC20-121-300 E 5](#) and household sharps collected at sharps drop boxes in accordance with [9VAC20-121-300 E 1](#);

2. Regulated medical waste shall not be treated onsite; and

3. Regulated medical waste that is stored on a loading dock or in areas designated for loading shall be packaged, marked, and labeled for transport and shall not be stored in loading areas for more than 24 hours.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-130. Reusable container requirements.

A. The requirements of this section shall be implemented whenever regulated medical waste is conveyed in reusable carts or containers.

B. The waste in the cart or container shall be packaged and labeled in accordance with [9VAC20-121-110](#).

C. Reusable carts and containers must be constructed of smooth, easily cleanable materials that are impervious to liquids and made of materials designed to withstand exposure to hot water or chemical disinfectants. A plastic bag shall not be reused.

D. Use of reusable carts and containers and any automated or mechanical cleaning and disinfection systems shall maintain the integrity of the packaging at all times, prevent damage, leakage, and spills and provide protection from the elements, vectors, and trespassers.

E. Persons cleaning and disinfecting reusable carts and containers shall wear appropriate personal protective equipment.

F. Immediately following each time a container is emptied and prior to being reused, all reusable carts and containers, including reusable suction canisters and fluid carts that receive blood, shall be both thoroughly cleaned and disinfected. Cleaning shall be conducted with detergent and water using an agitation method or by pressure and movement to remove all waste and visible contamination from all inner and outer surfaces of the container. At least one of the following methods shall be used for disinfection:

1. Utilizing an EPA-registered general or broad-spectrum disinfectant following manufacturer's label instructions;

2. Exposure to heated rinse water at a minimum of 180°F (82°C) and a maximum 195°F (90°C) for a minimum of 15 seconds, or until the surface reaches a temperature of 160°F (71°C); or

3. Immersion in or rinsing with, one of the following chemical sanitizers for a minimum of three minutes:

a. Hypochlorite solution (500 ppm available chlorine);

b. Phenolic solution (500 ppm active agent);

c. Iodophor solution (100 ppm available iodine);

- d. Quaternary ammonium solution (400 ppm active agent); or
  - e. Other organic, plant-based, or nonchemical disinfectant registered by EPA.
- G. All wash water from cleaning and disinfection shall be contained and discharged directly to an approved sanitary sewer system.
- H. Reusable carts and containers shall not be reused if there are cracks, holes, damage, or other defects, including to a lid or locking mechanism or if contamination or waste residuals are present.
- I. Reusable carts or containers used for the holding or storage of regulated medical waste shall not be used for any other purpose.
- J. When reusable carts or containers containing regulated medical waste are used for offsite transport, all aspects of the cart or container management shall comply with federal Department of Transportation Hazardous Material Regulations, 49 CFR Parts 171 through 180, as applicable.
- K. Reusable carts or containers that are damaged, defective, or ready to be discarded shall not be disposed of as solid waste unless they are cleaned and disinfected in accordance with this section, and all regulated medical waste labeling is removed or covered, prior to disposal. Containers unable to be cleaned and disinfected must be treated as regulated medical waste.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-140. Management of spills of regulated medical waste.

A. Any person or facility handling, generating, storing, transporting, transferring, treating, or disposing of regulated medical waste shall immediately address all spills of regulated medical waste, incidents or emergencies, maintenance events, and nonconformances that could have an impact on the management of regulated medical waste at the facility.

B. Anyone handling regulated medical waste shall maintain a spill containment and cleanup kit onsite within the vicinity of any area where regulated medical waste is managed, and the location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting regulated medical wastes are required to carry a spill containment and clean up kit in the vehicle whenever regulated medical wastes are conveyed. A spill containment and cleanup kit shall consist of at least the following items:

1. Material designed to absorb spilled liquids, and the amount of absorbent material shall be that having a capacity, as rated by the manufacturer, of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or 10 gallons, whichever is less;
2. In a sprayer capable of dispersing its charge in a mist and a stream at a distance, at least one gallon of an EPA-registered hospital grade disinfectant effective against mycobacteria, unless it can be demonstrated that an alternate EPA-registered disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected;
3. Enough red plastic bags to double enclose at least 150% of the maximum load managed (up to a maximum of 500 bags) that meet the applicable requirements of 49 CFR Part 173, including the ASTM 125 pound drop test for filled bags (D959) or an exemption approved by the U.S. Department of Transportation and are accompanied by seals and labels. These bags shall be large enough to overpack any box or container normally used for regulated medical waste management by that generator, handler, or facility;
4. Appropriate personal protective equipment, such as puncture and leak resistant gloves, safety glasses or face shield, protective coveralls or bib, protective footwear, and mask or respiratory protection as needed; and
5. For vehicles only, a first aid kit, fire extinguisher, boundary marking tape, lights, and other appropriate safety equipment.

C. Following any spill or release of regulated medical waste or its discovery, the following procedures shall be implemented:

1. Take appropriate precautions to ensure personnel do not come into contact with any contaminants by wearing appropriate personal protective equipment.
2. Repackage spilled regulated medical waste in accordance with the packaging requirements in [9VAC20-121-110](#).
3. Transport any regulated medical waste by a transporter that meets the requirements of [9VAC20-121-150](#).
4. Clean and disinfect all areas and materials having been contacted by regulated medical waste using an EPA-registered hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated that an alternate

EPA-registered disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected.

5. Take necessary steps to replenish the spill containment and cleanup kit.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-150. Transportation of regulated medical waste.

A. The requirements of this section apply to the transportation of regulated medical waste including by intermediate transporters and generators who transport their own waste offsite.

B. All transporters of regulated medical waste must comply with the general handling requirements in [9VAC20-121-100](#).

C. Regulated medical waste shall be transported in accordance with the applicable requirements for shipping papers, packaging, labeling, marking and vehicle placarding in accordance with the U.S. Department of Transportation Hazardous Materials Regulations, 49 CFR Parts 171 through 180. No person shall transport or receive for transport any regulated medical waste that is not packaged and labeled fully in accordance with the U.S. Department of Transportation Hazardous Materials Regulations. Reusable carts or containers used to transport regulated medical waste shall meet the requirements of the U.S. Department of Transportation Hazardous Materials Regulations and must be sealed, puncture resistant, and leak proof.

D. Transportation of regulated medical waste shall maintain the packaging in an upright and stable configuration to minimize the potential for spills. The integrity of the containers must not be compromised by the stacking arrangement.

E. All vehicles and equipment used in the transportation of regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste, and the cargo carrying body must be secured except when loading and unloading.

F. Surfaces of vehicles and equipment used to transport regulated medical waste must be clean and impermeable to liquids if those areas are involved with the management of the waste. Carpets and floor coverings with cracks or gaps shall not be used. Vehicles used to transport regulated medical waste shall be clean and maintained in an orderly condition, free of standing liquid and debris, in those areas involved with the management of the waste.

G. Storage, transport, and transfer to, from, and between vehicles and equipment shall be under a cover or packaged in a container that protects the waste from the elements and over a floor or bermed pavement that will contain leaks and spills of liquid from the waste. All effluent, wash water, and other runoff shall discharge directly to or through a holding tank to an approved sanitary sewer system. A cover, floor, or pavement is not required if the activity is transient in nature, such as in the case of spill cleanup or collection of waste packages from professional offices for transport.

H. All vehicles transporting regulated medical waste must carry a spill containment and cleanup kit in the vehicle as specified in [9VAC20-121-140 B](#), whenever regulated medical wastes are conveyed. Following a spill of regulated medical waste or its discovery, the procedures specified in [9VAC20-121-140 C](#) shall be implemented.

I. Any vehicle parked 24 hours or more during transport will be considered a regulated medical waste transfer station subject to the requirements of Part IV ([9VAC20-121-200](#) et seq.) of this chapter. Unless exempt under [9VAC20-121-300 E](#), no storage during transport will be allowed without a permit issued in accordance with the procedures in Part V ([9VAC20-121-300](#) et seq.) of this chapter.

J. All vehicles and equipment used to transport regulated medical waste must be thoroughly cleaned and disinfected before being used for any other purpose and prior to any transfer of ownership. Disinfection shall include using an EPA-registered hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated that an alternate EPA-registered disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected. Any areas of vehicles or equipment that are visibly contaminated, or that become contaminated as a result of a spill, must be immediately decontaminated in accordance with [9VAC20-121-140](#).

K. Transport of regulated medical waste by the United States Postal Services that fully complies with 39 CFR 111 shall be considered to be transportation in compliance with this chapter if:

1. The generator maintains a complete and legible copy of the manifest or mail disposal service shipping record for a period of three years. Disposer's certification and other tracking items must be completed and shown on the copy;

2. The addressee is a facility permitted by all the appropriate agencies of the Commonwealth or the host state; and
3. No package shall be more than 35 pounds by weight.

L. Category A waste shall be managed in accordance with the requirements of [9VAC20-121-160](#).

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-160. Management of Category A waste.

A. Category A waste shall be managed in accordance with the requirements of this section.

B. Overarching Planning Considerations and Waste Generator Information and Responsibilities for Category A waste are specified in Sections 3 and 5 of Managing Solid Waste Contaminated with a Category A Infectious Substance. In addition to the general management requirements for regulated medical waste in Part III ([9VAC20-121-100](#) et seq.), all Category A waste shall be handled in accordance with the following additional requirements:

1. Every effort shall be made to minimize the amount of Category A waste generated. Category A waste shall be physically separated, if practical, from other types of waste at the point of origin. When other types of regulated medical waste are mixed with Category A waste, the mixture shall be managed as Category A waste. Category A wastes not suitable for conventional treatment methods, such as batteries, electronics, and oxygen cylinders, shall be segregated from other waste at the point of generation for special handling.
2. All handling, storage, transfer, and treatment of Category A waste must be conducted in areas with cleanable and impermeable surfaces. Carpets and floor coverings with cracks or gaps shall not be used. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement.
3. Equipment and handling techniques that could potentially cause bioaerosols, such as cart tipping, slides, conveyors, and mechanical cleaning or disinfection systems, shall not be used for Category A waste unless the movement and impact is controlled to maintain the integrity of the packaging, prevent exposure to the waste, and any aerosol, bioaerosol, or mist caused by the process is collected and treated or filtered.
4. Category A waste shall not be conveyed in reusable carts or containers unless the containers are subsequently cleaned and disinfected in accordance with [9VAC20-121-130](#) using an EPA-registered disinfectant appropriate for the type of Category A waste managed and materials being disinfected.
5. All spills of Category A waste shall be cleaned and disinfected in accordance with [9VAC20-121-140](#) using an EPA-registered disinfectant appropriate for the type of Category A waste managed and materials being disinfected.
6. Category A waste shall be stored in accordance with the requirements of [9VAC20-121-120](#) B and C. Packages or containers of Category A waste shall not be stacked.
7. A generator storing 250 gallons or more of Category A waste shall notify the department within 24 hours of exceeding 250 gallons. At least once per calendar week, accumulated Category A waste shall be treated onsite in accordance with this section or shipped offsite to a facility permitted to receive it for treatment or disposal. No Category A waste shall be stored onsite for more than 10 calendar days unless an extended storage timeframe is approved by the department. Records shall be maintained in accordance with [9VAC20-121-100](#) I.
8. The regulated medical waste transfer station or treatment facility shall notify DEQ of receipt of any Category A waste in accordance with [9VAC20-121-340](#).

C. Waste Transporter Information and Responsibilities for Category A waste are specified in Section 6 of Managing Solid Waste Contaminated with a Category A Infectious Substance. Packaging and labeling of Category A waste for transport must comply with the more stringent packaging standards of 49 CFR Parts 171 through 180 of the HMR, or may require a Department of Transportation special permit for an exception to the HMR requirements to allow for alternative packaging to accommodate the waste.

D. Waste Treatment Information and Responsibilities for Category A waste are specified in Section 7 of Managing Solid Waste Contaminated with a Category A Infectious Substance. In addition to the general treatment requirements for regulated medical waste in Part IV ([9VAC20-121-200](#) et seq.), all Category A waste shall be treated in accordance with the following additional requirements:

1. A facility shall only receive Category A waste for processing or treatment upon specific approval from the director or by specific provisions within the facility's permit.

2. Prior to treatment of any Category A waste, the facility shall notify DEQ and conduct additional validation testing in accordance with [9VAC20-121-260](#) and an approved treatment plan that is specific to the Category A waste stream and packaging types that will be received.
3. The treatment method and operating parameters shall be appropriate and effective for the type of Category A waste being managed. Treatment units that employ a mechanical process, such as grinding or shredding, prior to treatment or integral to the treatment unit, may not be appropriate for Category A waste streams. The facility shall demonstrate that the process prevents employee exposure to the waste; contains any aerosol, bioaerosol, or mist caused by the process; and treats or filters any air evacuated from the chamber during processing.
4. The facility shall not receive or treat Category A waste until the department has reviewed and approved the validation results, operating parameters, and protocols to be used for the treatment unit.
5. Treatment of Category A waste shall only be in accordance with the operating parameters and protocols approved by the department.
6. Challenge testing shall be performed and documented for every load containing Category A waste. The facility may request an alternate challenge test frequency once a high level of confidence is established that the Category A waste is being effectively treated.
7. The owner or operator shall provide a certification that the regulated medical waste management plan demonstrates protocols specific to the Category A waste stream to be treated and meets all additional standards of Part III ([9VAC20-121-100](#) et seq.) and Part IV ([9VAC20-121-200](#) et seq.), as applicable, in accordance with [9VAC20-121-330](#). The plan shall specify if and how management protocols for Category A waste differ from existing protocols for routinely received regulated medical waste, including how treated wastes will be disposed. The certification shall also include a statement that the emergency contingency plan has been provided to the local police and fire departments, local emergency manager, and local emergency health coordinator.

E. Final Disposal Information and Responsibilities for Category A waste are specified in Section 8 of Managing Solid Waste Contaminated with a Category A Infectious Substance. Category A waste shall be disposed of in accordance with the following requirements:

1. Category A waste that has been treated in accordance with the special requirements of this section is no longer Category A waste or regulated medical waste. Category A waste treated in accordance with this section is solid waste and shall be disposed of at a permitted solid waste disposal facility, provided the disposal is in accordance with the Solid Waste Management Regulations ([9VAC20-81](#)) and the facility's permit.
2. Category A waste not treated in accordance with this chapter shall not be transported to, received for transport, or disposal by, or disposed of in, any solid waste management facility.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

#### Part IV

#### Standards for Regulated Medical Waste Transfer Stations and Treatment Facilities

#### 9VAC20-121-200. General and applicability.

- A. Any person who designs, constructs, or operates any regulated medical waste transfer station or treatment facility not otherwise exempt under [9VAC20-121-300](#) E shall obtain a permit-by-rule pursuant to this chapter prior to operation and comply with the requirements of this part. Further, all applications pursuant to this chapter shall demonstrate specific means proposed for compliance with requirements set forth in this part.
- B. All facilities, except exempted facilities, shall be maintained and operated in accordance with the permit-by-rule status pursuant to this chapter. All facilities shall be maintained and operated in accordance with the approved design and intended use of the facility.
- C. Hazardous wastes shall not be managed or disposed in facilities subject to this regulation unless specifically authorized by the facility permit or the director and managed in accordance with [9VAC20-60](#). Any material from a state other than Virginia that is classified as a hazardous waste in that state shall be managed as hazardous waste in accordance with [9VAC20-60](#).

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-210. Siting requirements.

A. The siting of all regulated medical waste transfer stations or treatment facilities shall be governed by the standards as set forth in this section. These facilities shall:

1. Be adjacent to or have direct access to roads that are paved or surfaced and capable of withstanding anticipated load limits;
2. Not be sited or constructed in areas subject to base floods;
3. Shall not be closer than:
  - a. 50 feet to any property boundary;
  - b. 50 feet to any perennial stream or river;
  - c. 200 feet to any residence or recreational park area; or
  - d. 200 feet to any health care facility, school, or similar type public institution, unless the facility is located at the health care facility, school, or similar type public institution.

B. The site of a regulated medical waste transfer station or treatment facility shall provide room to minimize traffic congestion and allow for safe management of regulated medical waste and safe operation of the facility.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-220. Design and construction requirements.

A. The design and construction of all regulated medical waste transfer stations or treatment facilities shall be governed by the standards as set forth in this section. These facilities shall have:

1. An access road suitable for loaded collection vehicles in all weather conditions from the entrance to the unloading or receiving area of the facility.
2. Onsite queuing capacity for the expected traffic so that the waiting collection vehicles do not back up onto the public road.
3. Unloading and loading areas of an adequate size and design to facilitate efficient transfer of regulated medical waste to and from collection vehicles and the unobstructed movement of vehicles.
4. Access controls such as perimeter security fencing, gates, locks, badge systems, or other controls to limit access to areas used to store, transfer, or treat regulated medical waste to only those persons specifically designated to manage regulated medical waste.
5. Adequate lighting so that operating personnel can exercise site control. Lighting may be provided by portable equipment as necessary.
6. Covered areas with cleanable and impermeable surfaces for handling, storage, transfer, and treatment of regulated medical waste and the cleaning and disinfection of reusable containers. These areas shall not be carpeted or have floor coverings with cracks or gaps. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement.
7. Bermed pavement, a liquid retaining lip, or equivalent controls at loading docks and near rolling or bay doors to contain potential leaks and spills of regulated medical waste or other liquids.
8. Floors sloped or graded to drain such that all effluent, wash water, and other runoff from storage and processing areas, treatment equipment, waste compactors, and reusable container cleaning and disinfection areas is contained and discharged directly to an approved sanitary sewer system.
9. Ventilation that discharges to minimize human exposure to the waste.
10. A water supply shall be provided for cleaning purposes.
11. Fire alarm and protection systems capable of detecting, controlling, and extinguishing any and all fires.
12. Fixed radiation detectors in a location as close as practicable to the incoming waste loads and in an appropriate geometry to monitor all waste prior to storage, transfer, or treatment. A fixed radiation detector is not required at captive regulated medical waste management facility

if the facility demonstrates that there is no potential for generation or management of radioactive materials or wastes. Demonstration shall include a certification that there is no radiation producing equipment or material onsite.

B. Effluent, wash water, and other runoff from the facility shall not be permitted to drain or discharge into surface waters except when authorized under a VPDES permit issued pursuant to [9VAC25-31](#).

C. Slides, cart tipplers, conveyors, and similar equipment used to move regulated medical waste must be designed and constructed such that the movement and impact is controlled to maintain the integrity of the packaging at all times and prevent damage, leakage, and spills. Trash chutes shall not be used to manage regulated medical waste.

D. Any areas used for the storage of regulated medical waste shall be designed in accordance with [9VAC20-121](#)-120 and have sufficient storage capacity for the maximum anticipated storage amount based on the amount of daily incoming waste and maximum length of time in storage.

E. All facilities that manage reusable containers or carts for regulated medical waste shall have designated areas for manual or mechanical cleaning and disinfection that comply with the requirements of [9VAC20-121](#)-130.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-230. Operation requirements.

A. The operation of regulated medical waste transfer stations or treatment facilities shall be governed by the standards as set forth in this section.

B. The regulated medical waste transfer station or treatment facility shall maintain and operate in accordance with a regulated medical waste management plan that meets all requirements of [9VAC20-121](#)-330. This plan shall be reviewed and recertified annually, within one year from the date of the last certification, to ensure consistency with current operations and regulatory requirements, and shall be made available for review by the department upon request. If the applicable standards of this chapter and the facility's operations plan conflict, this chapter shall take precedence.

C. The facility must operate to comply with the general handling requirements of [9VAC20-121](#)-100.

D. All regulated medical waste shall be packaged, labeled in accordance with [9VAC20-121](#)-110 and managed in accordance with the storage conditions and timeframes required by [9VAC20-121](#)-120. The facility shall employ methods to track and document specific incoming waste throughout the duration of storage, treatment or transfer, and shipment offsite.

E. All facilities that manage reusable carts or containers for regulated medical waste shall comply with the requirements of [9VAC20-121](#)-130 and maintain onsite an adequate water supply and sufficient quantity of detergent and EPA-registered disinfectant or other approved materials, as applicable.

F. Except for reusable containers authorized by the department to be opened, regulated medical waste containers must not be opened or unpackaged unless approved as part of the consolidation or treatment process.

G. The facility shall immediately address all spills of regulated medical waste, incidents or emergencies, maintenance events, and nonconformances that could have an impact on the management of regulated medical waste. Spill containment and cleanup kits shall be maintained as required by [9VAC20-121](#)-140 B, and immediately following a spill of regulated medical waste or its discovery, the procedures specified in [9VAC20-121](#)-140 C shall be implemented.

H. Damaged or leaking packages of regulated medical waste shall either be properly repackaged prior to storage and subsequent shipment offsite or contained and treated onsite within 24 hours if the facility is permitted for treatment operations.

I. Transportation of regulated medical waste is subject to the requirements of [9VAC20-121](#)-150.

J. Waste must not be accepted unless it is allowed in accordance with the permit-by-rule issued and the regulated medical waste management plan and there is sufficient storage, transfer, or treatment capacity. The amount of regulated medical waste received and stored at the facility shall not exceed the permit process rate and designed storage capacity.

K. Regulated medical waste transfer stations and treatment facilities regulated under this part shall implement an unauthorized waste control program in accordance with their written plan as required by [9VAC20-121](#)-330 and the following provisions:

1. Prior to managing regulated medical waste or using process equipment, and at least annually, within one year from the date of the last training, the facility shall provide training to staff to recognize, segregate, properly manage, document, and report receipt of waste not authorized to be managed by the facility's permit.
  2. If unauthorized waste is observed in the waste delivered to the facility prior to unloading, the owner or operator must refuse to accept the waste.
  3. If the unauthorized waste is observed in the waste at the facility or delivered to the facility, the owner or operator shall segregate it, notify the generator (if applicable), document the incident in the operating record, make necessary arrangements to have the material managed in accordance with applicable federal and state laws, and notify the department of the incident to include the means of proper handling, in accordance with the reporting procedures of [9VAC20-121-340](#).
  4. Any unauthorized waste accepted by the owner or operator shall be managed in accordance with applicable federal or state laws and regulations. The facility must carefully store the waste in a designated storage area within the facility separate from untreated regulated medical waste and treated regulated medical waste. Unauthorized waste that has been segregated and stored shall be adequately secured and contained to prevent leakage or contamination to the environment. The facility shall have the unauthorized waste removed or properly managed no later than 10 calendar days after discovery unless an alternate timeframe up to 30 days is approved by the department. Handling and management of the unauthorized waste, including segregation, removal, and transportation, shall be by a person authorized to manage such waste and shall be transferred, treated, or disposed of at a permitted waste management facility approved to receive it.
  5. The facility must maintain a record of all unauthorized waste accepted at the facility, the date accepted, the type of waste, date of transfer, treatment, or disposal, management method, and the name, address, and telephone number of the final treatment or disposal facility.
- L. Radiation detection equipment shall be operated and maintained in a manner that ensures all incoming waste is screened and the measurements are meaningful and fulfill the objectives for detecting radiologically contaminated waste. If fixed radiation detectors become inoperable, repairs shall be made as soon as practicable, and appropriate portable equipment shall be used to screen incoming waste loads until the equipment is repaired.
- M. Untreated waste, radioactive waste, hazardous waste, and any unauthorized waste must be segregated and stored in clearly identified containers. Category A waste shall be managed in accordance with the requirements of [9VAC20-121-160](#).
- N. The facility shall be operated to maintain the design and construction standards as required by [9VAC20-121-220](#).
- O. All areas used to transfer or treat regulated medical waste shall have prominent signage or markings displayed on the door or access point to indicate that the space is used to manage regulated medical waste, and those areas shall be secured to prevent unauthorized access.
- P. Floors and areas used for the handling, tipping, storage, transfer, or treatment of regulated medical waste and reusable container cleaning must be kept clean, in an orderly condition, and free of standing liquid and debris.
- Q. Effluent, wash water, and other runoff from facility floors, storage and processing areas, treatment equipment, waste compactors, and reusable container cleaning and disinfection areas shall be contained and discharged directly to an approved sanitary sewer system. Effluent, wash water, and other runoff from the facility shall not be permitted to drain or discharge into surface waters except when authorized under a VPDES permit issued pursuant to [9VAC25-31](#).
- R. All infrastructure and equipment shall be properly maintained and operated as designed and approved in the facility's permit. Facility maintenance must include annual calibrations of parametric controls, including recording devices and temperature and pressure gauges; overall cleaning (the facility, vehicles, and processing systems); servicing of exhaust lines and drains; ensuring the proper functioning of pressure and safety valves, and water, steam, disinfectant and electrical lines; replacing gaskets as needed to ensure a complete seal at all times; ensuring floor drains are maintained such that liquid is free-draining at all times; and maintaining proper functioning of mechanical waste handling systems, conveyors and shredders, HEPA, and other ventilation and filtration devices, and radiation monitoring devices, as applicable.
- S. Adequate numbers and types of properly maintained equipment shall be available for operation. Provision shall be made for substitute equipment to be available, except for treatment units which must be approved by the department, or the emergency contingency plan implemented to achieve compliance with this chapter, as applicable, within 24 hours should the former become inoperable or unavailable. Operators with training appropriate to the tasks they are expected to perform and in sufficient numbers for the complexity of the site shall be on the site whenever it is in operation.
- T. Safety hazards to operating personnel shall be controlled through an active safety program consistent with the requirements of 29 CFR Part 1910, as amended.
- U. Each facility shall conduct monthly inspections of all major aspects of facility operations necessary to ensure compliance with the requirements of this chapter. Records of these inspections must be maintained in the operating record and available for review in accordance with [9VAC20-121-340](#). If a deficiency or release is identified during an inspection, the owner or operator must document it on the self-inspection checklist, provide a remedy for the issue as soon as feasible, and document repairs and remedial actions, including the date implemented. The following aspects of the facility shall be inspected on a monthly basis whenever the facility is in operation:

1. Each component of the processing equipment, treatment system, and infrastructure;
  2. Spill containment and cleanup kit and any other decontamination materials;
  3. Safety and emergency equipment, including radiation detection equipment, fire alarm and protection systems, fire extinguishers, eyewash stations, or other equipment;
  4. Waste storage areas and loading and unloading areas;
  5. All floors and floor drains and any areas and inventory for managing, cleaning, and disinfecting reusable carts or containers;
  6. Proper use of personal protective equipment by all employees;
  7. Monitoring for pests and vermin, litter, blowing debris, odor, dust, breached containers, and spills; and
  8. Any areas in which significant adverse environmental or health consequences may result if breakdown occurs.
- V. Prior to managing regulated medical waste or using process equipment, and at least annually, within one year from the date of the last training, the facility shall provide all operators with training on the procedures for managing regulated medical waste specific to the transfer or treatment process used, including:
1. General handling of regulated medical waste and use of personal protective equipment;
  2. Packaging, labeling, and storage of regulated medical waste;
  3. Cleaning and disinfection of reusable containers;
  4. Facility housekeeping and management of spills;
  5. Overall process and mechanical operation of any equipment used ;
  6. Emergency contingency plan procedures, in case of system failure or other emergency ; and
  7. In addition to the requirements of subdivisions 1 through 6 of this subsection, treatment facility operators shall be trained on the operation of any treatment units and procedures for conducting periodic challenge testing.

W. The facility shall retain records in accordance with [9VAC20-121-340](#). Records shall be retained for three years and available for review as requested by the department.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-240. Treatment standards.

A. Prior to disposal or recycling, all regulated medical waste, including its packaging, must be treated by a department approved regulated medical waste treatment process. Any method used for the treatment of regulated medical waste must be verifiable to render the waste noninfectious in a manner that is protective of human health and the environment. Untreated regulated medical waste shall not be recycled or disposed of in a solid waste landfill or other solid waste management facility.

B. The requirements in this subsection are applicable to all treatment methods. Additional requirements are provided in subsections C through I of this section and are dependent on the type of treatment used.

1. The treatment method and operating parameters shall be appropriate and effective for the type of waste being managed.
  - a. Human pathological and anatomical waste, including tissues, organs, body parts, and other related waste and animal carcasses shall be treated by incineration unless an alternative treatment process is approved by the department. Alkaline hydrolysis is an alternative treatment process that may be considered for treatment. Pathological waste in a liquid fixative may require special management, such as decanting the liquid for separate disposal, incineration, or management as hazardous waste if applicable.
  - b. Thermally resistant waste, including solidified liquids and bulk animal bedding, requires approval of treatment operating parameters on a case-by-case basis.
  - c. Category A waste shall be managed in accordance with the requirements of [9VAC20-121-160](#).

d. Waste contaminated with toxins and toxin waste solutions (depending on the toxin) can be inactivated by incineration or extensive autoclaving, or by soaking in suitable decontamination solutions. Toxin inactivation procedures shall not be assumed to be 100% effective without validation using specific toxin bioassays.

2. Treatment equipment shall include built-in automatic controls and fail safe mechanisms to ensure the waste cannot bypass the treatment process.

3. Size reduction, grinding, shredding, or puncturing of containers is permissible if integral to the treatment unit and shall be done with safe and sanitary methods. Nothing in this section shall prevent the use of devices that grind, shred, or compact to reduce volume at the point of generation and prior to enclosing the regulated medical waste in plastic bags and other required packaging; however, the waste remains regulated medical waste. The facility shall demonstrate that devices are constructed and operated in a manner that prevents employee exposure to the waste; contains any aerosol, bioaerosol, or mist caused by the process; and treats or filters any air evacuated from the chamber during processing. Appropriate means must be employed to appropriately protect workers and contain the waste when unloading regulated medical wastes from such a device.

4. If grinding, shredding, or size reduction or puncturing of packaging takes place prior to treatment, it shall occur in a closed unit immediately preceding the treatment unit. If grinding, shredding, or size reduction takes place following treatment, it must occur within 24 hours of leaving the treatment unit. Transfer from a grinder or shredder to or from a treatment unit shall be under forced draft ventilation that removes fumes from the operations area to a safe discharge.

5. All process units for the preparation or treatment of regulated medical waste shall be in closed vessels designed to operate under a negative pressure atmospheric control that filters all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with efficiency of 99.97% for 0.3 microns. Proper installation of filters shall be documented. Air and gases which have themselves been sterilized by the process are not required to pass through a filter.

6. All effluent must be discharged to an approved sanitary sewer system. Effluent from the facility shall not be permitted to drain or discharge into surface waters except when authorized under a VPDES permit issued pursuant to [9VAC25-31](#).

7. Only the types of regulated medical waste specified in the facility's permit shall be treated using the approved treatment unit. Treatment methods include:

a. Autoclaves (steam sterilization);

b. Microwaves;

c. Dry heat treatment;

d. Chemical treatment;

e. Alkaline hydrolysis;

f. Incineration; and

g. Alternate treatment technologies as reviewed and approved by the department in accordance with this chapter.

8. Prior to operation of any treatment unit, the facility must conduct validation testing in accordance with [9VAC20-121-260](#) and an approved treatment plan to establish the appropriate operating parameters for effective treatment of regulated medical waste. The results of the testing must be submitted to the department for review and approval in accordance with [9VAC20-121-320](#). The facility shall not receive or treat regulated medical waste until the department has approved the validation results, operating parameters, and protocols to be used for the treatment unit. Revalidation shall be conducted as required by [9VAC20-121-260](#).

9. Treatment units shall operate in accordance with the specified operating parameters and protocols set forth in subsections C through I of this section or alternate standards established through validation testing and approved by the department. Records of treatment shall be maintained in accordance with [9VAC20-121-340](#).

10. Periodic challenge testing shall be performed under full loading in accordance with [9VAC20-121-270](#) to evaluate the effectiveness of each treatment unit and treatment method.

11. Effective treatment of regulated medical waste must achieve a 6 Log<sub>10</sub> or greater reduction of the viable spore concentrations of the most appropriate bacterial species for the treatment method. Effective treatment is demonstrated by no growth in all treated biological indicators and growth in all untreated biological indicators during validation and periodic challenge testing.

12. The selection of the most appropriate biological indicator to utilize during validation and challenge testing of a treatment process shall be supported by referenced standards, guidelines, or information from peer reviewed journals related to the process.

a. Biological indicators shall utilize spores from one of the following bacterial species:

- (1) *Geobacillus stearothermophilus* (G.s.);
- (2) *Bacillus atrophaeus* (B.a.);
- (3) *Bacillus subtilis* (B.s.);
- (4) Other *Bacillus* species or spore forming bacteria from domestic or international culture collections; or
- (5) Organisms that demonstrate the necessary resistance for the treatment method, as approved by the department.

b. The facility shall use commercially prepared biological indicators, such as spore strips, spore suspensions, and self-contained biological indicators.

c. Biological indicators shall be placed in the most challenging location during validation and periodic challenge testing. Indicator ports, chambers, or other mechanisms shall be used for placement of the biological indicator when placement directly into the waste may be compromised by the treatment method, such as when shredding, grinding, or other mechanism is used. Ports and chambers shall be accessible by the operator.

d. When using the appropriate biological indicator, the number to be used shall be based upon the amount of waste to be processed in accordance with [9VAC20-121-260 D 7](#) (for validation) and [9VAC20-121-270 B](#) (for periodic challenge testing).

13. Parametric controls shall be used to monitor critical operational treatment parameters and provide a record of measurements that can be correlated to effective treatment.

14. Door alignment, gaskets, locking mechanisms, and other components of any treatment unit that utilizes a pressure vessel (such as an autoclave) shall achieve a complete seal during operation to prevent leaking of steam, liquid, or waste and avoid decreases in pressure or temperature that could cause isolated cold spots inside the unit.

15. In the event of power failure, interrupted, or incomplete treatment cycle, the facility shall investigate the cause of the failure and make any necessary repairs to resolve the issue prior to the next treatment cycle. Any waste in the treatment unit shall either be removed and managed as regulated medical waste or subjected to another full treatment cycle once repairs are made.

16. After each cycle, treated waste shall be removed from reusable treatment carts and containers. All reusable treatment carts and containers shall be cleaned on a periodic basis to remove the buildup of more than de minimis amounts of treated waste residual on cart and container surfaces.

C. The requirements in this subsection are applicable to autoclave treatment methods.

1. All autoclaves shall be operated at 100% saturated steam conditions at appropriate combinations of operating temperatures, pressures, and residence times, that have been demonstrated through validation testing to achieve reliable and effective treatment of microorganisms in regulated medical waste at design capacity. Longer treatment cycles may be needed for loads with liquids. Autoclave operating temperatures shall be greater than or equal to 250°F (121°C) at no less than 15 pounds per square inch of gauge pressure, and the minimum operating temperature and pressure shall be maintained during the residence time of the treatment cycle.

2. All autoclaves shall be equipped with continuous time, temperature, and pressure monitoring and recording.

3. For vacuum autoclaves, pre-vacuum shall be conducted such that all system air is fully evacuated a minimum of two times prior to the residence phase of the treatment cycle, during which all air is evacuated to ensure adequate steam exposure throughout the waste. Additional pre-vacuum pulls may be required based on certain waste or packaging types, and as determined through validation testing.

4. For gravity autoclaves, pressure pulsing must be performed to evacuate all air in the unit.

5. Validation and periodic challenge testing shall be performed using biological indicators utilizing spores from the bacterial species *Geobacillus stearothermophilus*.

D. The requirements in this subsection are applicable to microwave treatment methods.

1. Microwaving treatment shall incorporate pretreatment by shredding and steam injection or induction.

2. All microwaves shall be operated between 203°F and 212°F (95°C and 100°C) for a minimum of 45 minutes. Alternate operating temperatures and cycle times may be demonstrated through validation testing.

3. Microwave radiation power of the treatment process shall be at least six units each having a power of 1,200 watts or the equivalent power output.

4. Each microwave treatment unit shall be equipped to sense, display, and continuously record the temperature at the start, middle, and end of the treatment chamber.
5. Process temperatures at the exposure chamber entry and exit and the waste flow rate shall be continuously monitored, displayed, and recorded.
6. Validation and periodic challenge testing shall be performed using biological indicators utilizing spores from the bacterial species *Bacillus atrophaeus*.

E. The requirements in this subsection are applicable to dry heat treatment methods.

1. Dry heat systems shall be operated per the following operational standards:

- a. Temperature of not less than 320°F (160°C) for 120 minutes;
- b. Temperature of not less than 340°F (170°C) for 60 minutes; or
- c. Temperature of not less than 360°F (180°C) for 30 minutes.

Alternate operating temperatures and cycle times may be demonstrated through validation testing.

2. Each treatment unit shall be equipped to sense, display, and continuously record the temperature of the treatment chamber.
3. Unless otherwise approved by the department, no treatment unit employing dry heat as the main treatment process shall have a treatment chamber capacity greater than 1.0 cubic foot in volume.
4. Validation and periodic challenge testing shall be performed using biological indicators utilizing spores from the bacterial species *Bacillus atrophaeus*.

F. The requirements in this subsection are applicable to chemical treatment methods.

1. Operating standards for chemical treatment systems are dependent on the chemical concentration and exposure time. Facilities wishing to employ a chemical treatment system shall submit an alternate treatment technology petition per [9VAC20-121-250](#) to justify the proposed operating parameters. Once the petition is approved, chemical concentration and treatment time operating parameters shall be demonstrated through validation testing in the presence of the maximum anticipated organic waste content.
2. The facility shall maintain registration for the chemical used in the treatment system in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act, if required.
3. Containers holding chemicals shall be labeled in accordance with 40 CFR 156 (Labeling Requirements for Pesticides and Devices), and the facility shall maintain Safety Data Sheets for all chemicals related to the chemical treatment system.
4. Validation and periodic challenge testing shall be performed using biological indicators utilizing spores from the bacterial species *Bacillus subtilis* or *Bacillus atrophaeus*.

G. The requirements in this subsection are applicable to alkaline hydrolysis treatment methods. Alkaline hydrolysis is a process by which heat and pressure dissolve and sterilize regulated medical waste in a strong solution of sodium or potassium hydroxide (NaOH or KOH, respectively).

1. Alkaline hydrolysis shall only be used for treatment of human pathological and anatomical waste, including tissues, organs, body parts, other related waste, and animal carcasses.
2. Systems that operate above atmospheric pressure must employ a dissolution chamber that is a certified pressure vessel by the American Society of Mechanical Engineers (ASME).
3. Operating parameters for alkaline hydrolysis systems vary depending on the amount of regulated medical waste to be treated and the type of contamination:
  - a. To inactivate microbial pathogens, the waste must be heated to 212°F (100°C), and pressurized at 15 pounds per square inch for three hours;
  - b. To destroy transmissible spongiform encephalopathy (TSE), including bovine spongiform encephalopathy, the waste must be heated to 300°F (150°C) and pressurized at 70 pounds per square inch for six to eight hours.
  - c. Chemical concentration and treatment time shall be demonstrated through validation testing in the presence of the worst case organic material waste content.

4. Treatment shall ensure the complete dissolution of all tissue remains, if applicable, and any solids left shall be disposed of at a solid waste management facility permitted to receive it.

5. Validation and periodic challenge testing shall be performed using biological indicators utilizing spores from the bacterial species *Geobacillus stearothermophilus*.

H. The requirements in this subsection are applicable to incineration treatment methods.

1. All incinerators shall be permitted under regulations of the State Air Pollution Control Board and be in compliance with the regulations of that body.

2. All combustible regulated medical waste shall be converted by the incineration process into ash that is not recognizable as to its former character.

3. Analysis of ash and air pollution control residues:

a. Incinerator bottom ash and residues collected from air pollution control equipment shall be collected separately in leak resistant containers with runoff controls to prevent releases from the ash storage. Incinerator bottom ash and air pollution control residues shall be stored separately until sample testing per subdivision 3 b of this subsection is performed and the waste streams are determined to be a solid waste.

b. Testing requirements:

(1) Representative samples consisting of 250 milliliters of each waste stream shall be collected once every eight hours of operation of a continuously fed incinerator and once every batch or 24 hours of operation of a batch fed incinerator. Samples shall be collected during each 1,000 hours of operation or quarterly, whichever is more often, and samples shall be thoroughly mixed and seven random portions of equal volume shall be composited into one sample for laboratory analysis. This sample shall be tested in accordance with the methods established by the Virginia Hazardous Waste Management Regulations ([9VAC20-60](#)) for determining if a solid waste is a hazardous waste.

(2) In addition to subdivision 3 b (1) of this subsection, composite samples of incinerator bottom ash shall be tested for total organic content.

c. If ash or air pollution control residues are found to be hazardous waste (based on a sample and a confirmation sample) the waste ash shall be managed of as a hazardous waste in accord with the Virginia Hazardous Waste Management Regulations ([9VAC20-60](#)). The operator shall notify the department within 24 hours. No later than 15 calendar days following, the permittee shall submit a plan for treating and disposing of the waste on hand at the facility and all unsatisfactorily treated waste that has left the facility. The permittee shall include with the plan a description of the corrective actions to be taken to prevent further unsatisfactory performance. No ash or air pollution control residues subsequently generated from the incinerator waste stream found to be hazardous waste shall be sent to a nonhazardous solid waste management facility in the Commonwealth unless written approval of the director is obtained in accordance with Solid Waste Management Regulations ([9VAC20-81](#)).

d. If ash or air pollution control residues are found not to be hazardous waste by analysis, they may be disposed of in a solid waste landfill that is permitted to receive municipal solid waste or incinerator ash, provided the disposal is in accordance with the Solid Waste Management Regulations ([9VAC20-81](#)).

e. A log shall document the ash sampling, to include the date and time of each sample collected; the date, time, and identification number of each composite sample; and the results of the analyses, including laboratory identification. Results of analyses must be returned from the laboratory and recorded within four weeks following collection of the composite sample. The results and records described in this part shall be maintained for a period of three years, and shall be available for review.

I. Alternate treatment technologies as reviewed and approved by the department. All alternate treatment technologies approved by the director shall conform to the general treatment standards in subsection B of this section and any additional requirements the department imposes at the time of approval.

1. Any person who desires to use a chemical treatment technology per subsection F of this section or treatment technology, other than those described in subsections C, D, and E or subsections G and H of this section, shall petition the director for a review under [9VAC20-121-250](#).

2. If the director finds that the technology and application is in accordance with this part, the department may consider the facility for permitting.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-250. Alternate treatment technologies.

A. In accordance with [9VAC20-121-240 I](#), chemical treatment and other alternate treatment technologies may be approved for permitting if the department reviews the process and determines that the technology provides treatment in accordance with this chapter and protects public health and the environment, and if the department establishes appropriate conditions for their siting, design, and operation. This section establishes the criteria, protocols, procedures, and processes to be used to petition the director for review and to demonstrate the suitability of the proposed technology for the treatment of regulated medical waste.

B. Alternate treatment technologies are subject to the general treatment standards of [9VAC20-121-240](#) and the additional requirements of this section. To ensure effectiveness of the proposed chemical or alternate treatment technology, the applicant must demonstrate effective microbial and bacterial inactivation at a 6 log<sub>10</sub> or greater reduction for the microorganisms and spores listed in subsections C and D of this section through validation testing that meets the requirements of [9VAC20-121-260](#).

C. Microbial inactivation shall be demonstrated using one or more representative microorganisms from each microbial group:

1. For vegetative bacteria: either *Staphylococcus aureus* (ATCC 6538) or *Pseudomonas aeruginosa* (ATCC 15442).
2. For fungi: either *Candida albicans* (ATCC 18804), *Penicillium chrysogenum* (ATCC 24791), or *Aspergillus niger*.
3. For viruses: either Polio 2 or Polio 3, or MS-2 Bacteriophage (ATCC 15597-B1).
4. For parasites: either *Cryptosporidium* spp. oocysts or *Giardia* spp. Cysts.
5. For Mycobacteria: either *Mycobacterium terrae*, *Mycobacterium phlei*, *Mycobacterium bovis* (BCG) (ATCC 35743).

D. Bacterial inactivation shall be demonstrated for chemical, thermal, and irradiation treatment systems using spores from either *B. stearothermophilus* (ATCC 7953) or *B. subtilis* (ATCC 19659).

E. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration shall be used to demonstrate effective treatment. Effective treatment is demonstrated by no growth in all treated biological indicators and growth in all untreated biological indicators during validation and periodic challenge testing.

F. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation or grinding), quantitative measurement of effective treatment requires a two-step approach: Step 1, "Control"; Step 2, "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

1. Step 1 is:

- a. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.
- b. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals).
- c. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
- d. Plate recovered microorganism suspensions to quantify microbial recovery. (The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the microbial inactivation agent).
- e. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate a 6 log<sub>10</sub> or greater reduction.

2. Step 2 is:

- a. Use microbial cultures of the same concentration as in Step 1.
- b. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the microbial inactivation agent.
- c. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
- d. Plate recovered microorganism suspensions to quantify microbial recovery.

3. From data collected from Step 1 and Step 2, the level of microbial and bacterial inactivation shall be calculated based on the:

- a. Number of viable "Test" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit,

- b. Number of "Control" microorganisms (in colony forming units per gram of waste solids) that were not recovered after processing, and
  - c. Number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.
- G. To initiate the technology review process the applicant shall complete and submit DEQ Form RMWTP-01, Application for Evaluation and Approval of Regulated Medical Waste Treatment Technology to the department. The application shall be accompanied by:
- 1. A detailed description of the chemical or alternate treatment technology. The description must include:
    - a. A discussion of operating procedures and conditions, including, as applicable, treatment times, pressure, temperatures, chemical concentrations, irradiation doses, feed rates, and waste load composition;
    - b. A discussion of parametric controls, verifying effective treatment, and ensuring operator noninterference; and
    - c. A discussion of waste residues and by-products generated and methods of disposal or recycling.
  - d. The description shall be accompanied by the manufacturer's operations manual or equipment usage instructions, equipment specifications, and maintenance manual.
2. Documentation demonstrating the chemical or alternate treatment technology meets microbial and bacterial inactivation criteria specified under subsections B through F of this section. The documentation must include a description of the test procedures and calculations used in fulfilling required performance standards verifying effective treatment, of user verification methodology, and of microbial culturing protocols that ensure traceability, purity and concentration, and copy of all test results.
3. A chemical management plan describing all chemicals to be stored on site and include copies of Safety Data Sheets for all chemicals used for regulated medical waste treatment and EPA pesticide registration, if applicable.
4. Documentation providing occupational safety and health assurance.
- H. The applicant shall demonstrate that all required surrogate pathogens and resistant bacterial endospores are inactivated to criteria specified in subsections B through F of this section under the representative surrogate waste load compositions.
- I. The applicant shall demonstrate where the relationship between effective treatment, biological indicator data, and data procured from real-time parametric monitoring devices for the treatment unit.
- J. The review of the application will occur in accordance with this subsection.
- 1. After receiving an application that includes the information and demonstrations required in subsections A through I of this section, the department will perform an administrative review and determine whether the information received is sufficient to approve the proposed chemical or alternate treatment technology. If the information is deemed to be insufficient, the department will request that additional information be furnished.
  - 2. The applicant may submit the additional information requested or may demonstrate that the additional information should not be required. If the department agrees that the additional information is not required, the department will determine if the application is complete.
  - 3. After the application is deemed complete, the director may then issue a treatment technology approval. The approval shall be issued under the conditions specified in the manufacturer's instructions and equipment specifications, operating procedures, and conditions as outlined in the application, including, as applicable, treatment times, temperatures, pressure, chemical concentrations, irradiation doses, feed rates, and waste load composition. Any significant revision to these conditions will require reapplication for approval in accordance with this section.
  - 4. Following technology approval, any facility wishing to use the approved technology to treat regulated medical waste shall apply for and obtain the necessary permits in accordance with Part V ([9VAC20-121-300](#) et seq.).

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-260. Validation testing.

A. Prior to using any treatment system, the facility must conduct validation testing that employs the use of process controls, biological indicators, and process monitoring to establish operating parameters to demonstrate effective treatment of regulated medical waste.

B. Prior to validation testing, the owner or operator shall submit to the department a treatment plan containing the information required by [9VAC20-121-330 E](#). The plan shall demonstrate that the validation protocols for each treatment unit meet the standards of this section and shall indicate any additional protocols specific to the regulated medical waste to be treated, such as the use of packaging types that may affect treatment of the waste. Validation testing must be conducted in accordance with an approved treatment plan and the requirements of this section. The validation test results and operating parameters must be submitted to the department for review prior to acceptance of regulated medical waste for treatment.

C. To demonstrate reproducibility, a minimum of three separate treatment runs must be performed on three separate days, using three distinct loads, during which the department is present to witness at least one complete validation test run. All test runs shall meet the following requirements:

1. Operating parameters used during the tests must be consistent with the parameters that will be used during routine operation of the treatment process (e.g., cycle duration, temperature, pressure, chemical concentration, irradiation exposure time, or other treatment parameters as applicable).

2. Surrogate waste load composition (e.g., porosity, liquids, solids, moisture content, organic matter, thermal resistance, and type of packaging or containers) and waste load configuration (e.g., packing density and orientation) used during the tests must be consistent with the waste properties and loading process that will be used during routine operation. The surrogate waste load shall represent the most difficult waste anticipated to be treated during routine operation.

3. The weight and volume of the surrogate waste loads used during the tests must be consistent with the amount of waste that will be treated during routine operation. Validation testing must be performed at the treatment unit's full capacity unless an alternate load size is approved.

D. To assess treatment performance, the system must employ commercially-prepared biological indicators from the same lot or batch, each containing spores that demonstrate the necessary resistance for the treatment method, as determined by the department. The indicators must:

1. Have a minimum concentration of  $6 \log_{10}$  spores per biological indicator. The concentration must be higher and more thermally resistant than the bioburden routinely associated with the waste;

2. Include a supplier's certificate of performance (or certificate of analysis) that identifies the organism (genus, species, strain, and population) and, for thermal treatment systems (including autoclaves), the D-value and Z-value. The D-value must be 1.5 to 3.0 minutes, unless otherwise approved by the department, and the Z-value must be no less than 50°F (10°C);

3. Be appropriate for the type of waste and device (i.e., self-contained, suspension, or spore strip), including the shelf life, the carrier material and primary packaging, the culture medium (for self-contained biological indicators) and the media, growth, and culture conditions (for non-self-contained biological indicators);

4. Be compatible with the treatment process and have a resistance relative to the temperature, pressures, conditions, chemicals, or irradiation used in the process; the infectious agents on a substrate; the type and density of the waste to be treated; and its packaging;

5. Be placed in a carrier system (e.g., net bags, wrapped in a paper towel and encased in cotton batting or inside tennis balls, socks, or alloy containers with holes in them) designed to mimic the thermal resistance of the waste before placement into the package to be treated. Materials used to hold biological indicators must be similar to the waste to be treated, provide effective protection from damage or breakage or from otherwise being compromised, be loose in the bulk of the waste, and be easily retrievable at the end of each validation test run. Indicators shall not be placed in carrier systems that would enhance treatment or produce erroneous results (such as metal containers that would conduct heat);

6. Be placed throughout the waste load during each validation test at the coldest or most challenging locations within the treatment unit, where the sum of all influences on the microorganisms results in minimal inactivation for a defined waste load;

7. Be used in accordance with the quantity specified as follows, for each test run:

a. Three biological indicators per cycle for 0 to 110 pounds of waste per load;

b. Five biological indicators per cycle for 111 to 550 pounds of waste per load;

c. Seven biological indicators per cycle for 551 to 1,100 pounds of waste per load;

d. Nine biological indicators per cycle for 1,101 to 1,650 pounds of waste per load;

e. Eleven or more biological indicators per cycle, as determined by the department, for greater than 1,650 pounds of waste per load; and

f. One or more biological indicators from the same lot or batch to be left untreated and used as a control;

8. Be stored in accordance with the manufacturer's specifications when not in use. Expired biological indicators shall not be utilized.

9. Biological indicators in the form of paper strips must not be used in devices or areas where fluids can pool or puddle around the indicator. Self-contained biological indicators with vent caps must not be used where liquids may accumulate and contaminate the indicators.

10. Qualitative or quantitative biological indicators shall be used provided the operator or vendor of the technology provides evidence from such sources as peer reviewed journals that support the use of that particular indicator. Biological indicators requiring microbial bioassay to confirm effective treatment must be quantitatively analyzed after the treatment cycle. All self-contained biological indicators used for test runs must be evaluated for growth (e.g. qualitatively analyzed for color change) following incubation in accordance with the manufacturer's instructions.

E. Concurrent with biological indicators, the process must employ devices or instrumentation that demonstrates the treatment unit is achieving critical operating parameters for effective treatment. Process monitoring shall include:

1. Thermochemical indicators (e.g., tape, paper strips, or integrators) that demonstrate that the waste has been exposed to a certain temperature or chemical concentration;

2. Thermochemical recording devices (e.g., wireless data loggers, thermocouples, or chemical monitoring probes) that are placed in or on waste packages and that provide a measurable record of actual treatment conditions of the waste. The minimum number of thermochemical recording devices to be used during each validation test shall be at least one device per treatment bin plus one additional device in the treatment chamber; and

3. Parametric controls or monitoring devices integral to the treatment system that record critical operational treatment parameters and provide a record of measurements that can be correlated to effective treatment.

F. Effective treatment of regulated medical waste must achieve a 6 log<sub>10</sub> or greater reduction of the viable spore concentrations of the most appropriate bacterial species for the treatment method. Effective treatment is demonstrated by no growth in all treated biological indicators and growth in all untreated biological indicators during each test run. In certain situations where the waste poses a greater risk (e.g., a higher bioburden waste), the department may require a greater reduction.

G. The facility shall submit to the department for approval a summary of the validation test results demonstrating the treatment effectiveness and specifying the operating parameters based on the results of all validation test runs. The report shall describe the results of all validation test runs, including:

1. Date and time of all test runs, including the operator's name and cycle start and end times;

2. Surrogate waste load composition, configuration, and size;

3. Number, type, batch or lot number, expiration date, and placement of biological indicators, thermochemical indicators, and thermochemical recording devices; and

4. Results of all methods used to monitor operating parameters achieved throughout the treatment cycle and the accuracy of parametric monitoring devices, including copies of charts, graphs, or other read-outs from the treatment equipment and growth results of all treated indicators and untreated controls.

H. Validation testing must be repeated when any of the following occurs:

1. Failure of any treatment process to achieve operational parameters, such as time, temperature, or pressure during validation testing;

2. Failure to achieve microbial inactivation in any biological indicator during any treatment cycle during validation testing;

3. Failure of the untreated control indicator to show growth of the viable spore concentration;

4. Any modifications to any of the treatment process operational parameters, bioburden, waste mass, chemical type, concentration, irradiation or exposure time, type of waste to be treated, or mechanical or engineering changes to the treatment system from those assessed during the validation testing;

5. A failure identified in subdivision 1, 2, or 3 of this subsection during periodic challenge testing as identified by biological or process monitoring that occurs three or more times in a calendar year or during the first 30 days of actual operation;

6. A treatment device has been operational without a repeat validation for at least five years; or

7. A treatment device has not been used for at least one year.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

**9VAC20-121-270. Periodic challenge testing.**

- A. After initial validation testing and during routine operation, a regulated medical waste treatment facility shall perform periodic challenge testing under full loading to evaluate the effectiveness of each treatment device in accordance with procedures outlined in the facility's approved treatment plan.
- B. Periodic challenge testing shall be performed in accordance with the following requirements:
1. Biological indicators shall be used to periodically challenge test a load of regulated medical waste and must comply with all requirements of [9VAC20-121-260 D](#), with the exception of the quantity of biological indicators required under [9VAC20-121-260 D 7](#).
  2. Periodic challenge testing must include at least one-third of the number of appropriate biological indicators that are required for the validation test, or two indicators, whichever is greater, unless otherwise determined by the department. One or more additional biological indicators from the same lot or batch shall be left untreated and used as a control.
  3. The results of all periodic challenge testing shall be maintained for three years in accordance with [9VAC20-121-340](#) and shall include:
    - a. Date and time of all challenge tests, including the operator's name and cycle start and end times;
    - b. Number, type, batch or lot number, expiration date, and placement of biological and thermochemical indicators; and
    - c. Results of all methods used to monitor operating parameters achieved throughout the treatment cycle, including copies of charts, graphs, or other read-outs from the treatment equipment and growth results of all treated indicators and untreated controls.
  4. Effective treatment of regulated medical waste must be demonstrated by a 6 Log<sub>10</sub> or greater reduction of spore concentrations in all biological indicators in each periodic challenge test. A challenge test is considered a failure if any of the following occurs:
    - a. Failure of any treatment process to achieve operational parameters such as time, temperature, or pressure;
    - b. Failure to achieve microbial inactivation in any biological indicator during any treatment cycle. All biological indicators must show passing results (no growth in the viable spore concentration) after treatment or the challenge test is considered a failure; or
    - c. Failure of the untreated control indicator to show growth of the viable spore concentration.
- C. Any regulated medical waste treated during or after a challenge test shall be stored temporarily until challenge test results are obtained. Regulated medical waste shall not be shipped offsite until the challenge test is complete and shows passing results for all biological indicators.
- D. Unless otherwise approved by the department, for the first 30 days of actual operation, each treatment unit shall undergo challenge testing twice per day. The first load of each day shall be used for one of the required challenge tests.
- E. Following the first 30 days of actual operation, periodic challenge testing must be conducted at a minimum of once per week or every 40 hours of operation, whichever is greater.
- F. After six months of successful operation with no challenge test failures in weekly or 40- hour testing, challenge testing shall be conducted at least once per month.
- G. Any challenge test failures during the first six months of actual operation shall require a return to daily challenge testing for at least 30 operating days. After the first six months of actual operation, any challenge test failure shall require a return to challenge testing once per week or every 40 hours of operation, whichever is greater.
- H. Following any challenge test failure:
1. The waste shall continue to be managed as regulated medical waste and shall be retreated, stored temporarily until retreatment, or diverted to another approved facility for treatment or disposal. Regulated medical waste shall not be considered treated until a subsequent challenge test is conducted with passing results;
  2. The facility shall evaluate and correct any issues with the treatment cycle and unit prior to treating any additional waste;
  3. The facility shall notify the department of the failure in accordance with [9VAC20-121-340](#); and
  4. The facility shall increase the frequency of challenge testing in accordance with subsection G of this section.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-280. Disposal of treated regulated medical waste.

A. Regulated medical waste that has been treated in accordance with this part is no longer a regulated medical waste. Treated regulated medical waste is a solid waste. Treated waste may be compacted in a closed container in a safe and sanitary manner.

B. Treated waste shall be disposed of at a permitted solid waste disposal facility in accordance with the Solid Waste Management Regulations ([9VAC20-81](#)) and the solid waste disposal facility's permit. Regulated medical waste not treated in accordance with this chapter remains a regulated medical waste and shall not be transported to, received for transport or disposal by, or disposed in any solid waste management facility.

C. Where non-bulk treatment is used, treated waste shall be placed in sealed bags or containers that allow for visible assessment of treatment, such as clear bags or bags marked with sterilization indicators. The bags shall not be red in color. Opaque bags and bags with special labels are permissible if agreed upon in writing by the solid waste management facility receiving the treated waste. Treatment cart liners that are resistant to treatment conditions (such as temperature) may be used to package treated waste. Where bulk treatment is used and the solid waste is immediately placed or compacted in closed bulk solid waste management containers that are more than 64 gallons in volume, the repackaging of the solid waste in bags is not required. Treated waste shall not be repackaged as regulated medical waste.

D. The regulated medical waste treatment facility shall have a written treated waste disposal plan that shall be provided to each permitted solid waste management facility that will transfer, store, or dispose of the treated waste. The plan shall specify and include the following:

1. A description of how the treated waste will be packaged and transported to each solid waste management facility, including the types and colors of bags or containers used, and any special labeling if applicable;

2. The type of regulated medical waste treated, treatment method, and name, address, and telephone number of the treatment facility;

3. The name, address, and telephone number of any transfer stations or other intermediate facilities or locations where the treated waste will be transferred or temporarily stored prior to transport to a permitted solid waste disposal facility ;

4. The plan shall be updated and redistributed to receiving facilities when there are changes to the treatment process or facility operation that impact the plan.

5. The facility shall maintain records of distribution of the plan to all transfer, storage, or disposal facilities that manage the treated waste.

E. If treated residuals are determined to be hazardous, then the waste must be managed in accordance with the Virginia Hazardous Waste Management Regulations ([9VAC20-60](#)).

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-290. Closure requirements.

A. The owner or operator of a regulated medical waste management facility shall close the facility in a manner that minimizes the need for further maintenance, and controls, minimizes, or eliminates, to the extent necessary to protect human health and the environment, the post-closure escape of regulated medical waste, uncontrolled effluent, surface runoff, or waste decomposition products to the groundwater, surface water, or atmosphere.

1. When a unit that has been used for regulated medical waste management is to cease operations involving regulated medical waste, the unit and all related equipment, structures, and surfaces shall be thoroughly cleaned and disinfected. Cleaning shall be conducted with detergent and water. At a minimum, disinfection shall include using an EPA-registered hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated to the satisfaction of the department that an alternate EPA-registered disinfectant will be protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected.

2. All regulated medical waste, materials contaminated with waste constituents, and treatment residue shall be removed and disposed of in accordance with this chapter.

B. Closure plan and modification of plan.

1. The owner or operator of a regulated medical waste management facility shall have a written closure plan that meets the requirements of [9VAC20-121-330 G](#).
2. The owner or operator may amend the closure plan at any time during the active life of the facility. The owner or operator shall so amend the plan any time changes in operating plans or facility design affects the closure plan. The amended closure plan shall be placed in the operating record.
3. The owner or operator shall submit to the department the amended closure plan that was placed in the operating record.
4. At least 180 days prior to beginning closure of each unit, the owner or operator shall notify the director of the intent to close.
5. The owner or operator shall provide to the department a certification that the facility has been closed in accordance with the closure plan.

C. The owner or operator shall complete closure activities in accordance with the closure plan and within six months after receiving the final volume of wastes. The director may approve a longer closure period if the owner or operator can demonstrate that the required or planned closure activities will take longer than six months to complete, and that the owner or operator has taken all steps to eliminate any significant threat to human health and the environment from the unclosed but inactive facility.

D. The owner or operator shall post one sign notifying all persons of the closing and providing a notice prohibiting further receipt of waste materials. The sign shall remain in place until closure activities are complete. Further, suitable barriers shall be installed at former accesses to prevent new waste from being delivered.

E. The department shall inspect the facility to confirm that the closure is complete and adequate in accordance with this chapter. The department shall notify the owner of a closed facility in writing if the closure is satisfactory, or if unsatisfactory, shall require any necessary construction or such other steps as may be necessary to bring unsatisfactory sites into compliance with this chapter. Notification by the department that the closure is satisfactory does not relieve the operator of responsibility for corrective action to prevent or abate problems caused by the facility.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

Part V

Permitting of Regulated Medical Waste Management Facilities

9VAC20-121-300. Applicability.

A. Any facility operated for the transfer or treatment of regulated medical waste that is not exempt in accordance with this chapter, must hold a permit-by-rule from the department prior to commencement of operations.

B. Each regulated medical waste management facility permit-by-rule shall be limited to one site and shall be nontransferable between sites.

C. A new permit-by-rule is required when there is:

1. Any new regulated medical waste management facility; or
2. Any change in design or process of a regulated medical waste management facility that will result in a different type of facility. These changes may include a change from transfer to treatment facility, change of physical location, or change from captive to non-captive facility.

D. The director may grant a variance from any provision contained in this part to a permittee provided the requirements of Part VI ([9VAC20-121-400](#) et seq.) of this chapter are met.

E. The following regulated medical waste management activities are conditionally exempt from the requirements of this part provided no open dump, hazard, or public nuisance is created and wastes are managed in accordance with the requirements promulgated by other applicable state or federal regulations or the conditions provided in this section.

1. Household sharps may be collected in a sharps drop box located in a public restroom, airport, train station, health clinic, pharmacy, health department, police or fire station, community organization building, permitted solid waste management facility, or other location as a convenience to the public, as long as the following requirements are met:

- a. Sharps drop boxes shall only receive household sharps from individual home generators who choose to transport household sharps to the drop box. Sharps drop boxes shall not receive waste from collection vehicles or other entities that have collected waste from more than one real property owner;
  - b. All owners and operators of sharps drop boxes must comply with the general handling, packaging and labeling, storage, reusable container, spill cleanup, transportation, and Category A waste management requirements for regulated medical waste outlined in Part III ([9VAC20-121-100 et seq.](#)) of this chapter; and
  - c. Collected sharps shall be treated or disposed of as regulated medical waste in accordance with this chapter. Untreated sharps shall not be recycled or disposed of in a solid waste landfill or other solid waste management facility. Collected sharps that are shipped offsite as part of a mail-back program shall be transported in accordance with the requirements of 39 CFR 111 and [9VAC20-121-150 K](#).
2. Facilities that employ a treatment method to treat regulated medical waste onsite but subsequently package, label, and transport the waste offsite to be further managed as regulated medical waste are exempt from permitting in accordance with this chapter, but are subject to all other standards outlined in Part III ([9VAC20-121-100 et seq.](#)) for the management of regulated medical waste.
  3. Treatment systems (such as an effluent decontamination system) used to treat industrial or domestic sewage discharges in compliance with federal, state, or local pretreatment requirements as applicable. If the treatment unit separates solids from liquids prior to discharge, the solids shall be managed as regulated medical waste unless it meets an exemption in accordance with this chapter.
  4. Combustion of up to 10% by weight of regulated medical waste in a Virginia Solid Waste Management Regulations ([9VAC20-81](#)) permitted solid waste incinerator, thermal treatment, or waste to energy facility. Regulated medical waste must be an approved supplemental waste or included in an approved material review process in accordance with the State Air Pollution Control Board regulations and management of the regulated medical waste prior to addition to the incinerator, thermal treatment, or waste to energy unit must be in accordance with this chapter.
  5. Temporary offsite storage of regulated medical waste generated from an emergency cleanup for up to 72 hours, including in a locked vehicle, prior to transporting directly to a regulated medical waste management facility permitted to receive the waste for treatment, transfer, or disposal, provided that all regulated medical waste is:
    - a. Generated from an emergency or unplanned sudden or nonsudden spill or release of regulated medical waste requiring immediate response in order to protect human health or the environment, and the regulated medical waste was not generated by a health care professional or nonstationary health care provider;
    - b. Collected from not more than one individual regulated medical waste generator and is not received from collection vehicles or other entities that have collected waste from more than one real property owner;
    - c. Managed, stored, and transported in accordance with all requirements of Part III ([9VAC20-121-100 et seq.](#)) of this chapter, except for the storage timeframe which shall be no more than 72 hours; and
    - d. Not a Category A waste, hazardous waste, or radioactive waste.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-310. Permits by rule and emergency permits.

A. This subsection contains the requirements for permits-by-rule. The owner or operator of a facility described in subdivision A 1 of this section shall be deemed to have a regulated medical waste management facility permit if (i) the owner or operator submits the completed DEQ Form RMW PBR, Regulated Medical Waste Management Facility Permit-by-Rule Form, and all required information and attachments as detailed in subdivision A 2 of this section, and (ii) the department acknowledges completeness of the submittal per subdivision A 4 of this section.

1. Except for exempt facilities described in [9VAC20-121-300 E](#), the owner or operator of the following regulated medical waste management facilities shall apply for a permit-by-rule:
  - a. Regulated medical waste transfer stations as defined by this chapter, including when a vehicle transporting regulated medical waste will be parked for 24 hours or more during transport;
  - b. Facilities treating regulated medical waste employing a treatment method described in [9VAC20-121-240](#); and
  - c. Facilities treating regulated medical waste employing an alternate treatment method as described in [9VAC20-121-250](#).

2. The owner or operator of a regulated medical waste management facility shall submit the following information and documentation to the department:

a. To initiate the permit-by-rule application process, any person who proposes to establish a new regulated medical waste management facility, or modify an existing regulated medical waste management facility shall file a notice of intent with the director stating the type of facility for which the permit-by-rule application is made, the precise location of the proposed facility, and the intended use of the facility. The notice shall be in letter form and be accompanied by the following documents:

(1) A disclosure statement (DEQ Forms DISC-01 and DISC-02) identifying all key personnel as required by § [10.1-1408.1](#) of the Code of Virginia.

(2) A copy of the certification for at least one operator licensed by the Board for Waste Management Facility Operators as required by § [10.1-1408.2](#) of the Code of Virginia.

(3) A certification (DEQ Form CERT-01) from the governing body of the county, city, or town in which the facility is to be located stating, without qualifications, conditions, or reservations, that the location and operation of the facility are consistent with all applicable ordinances. No certification shall be required for the application for a modification to an existing permit-by-rule.

(4) The results of the public participation effort conducted in accordance with the requirements contained in subdivision A 3 of this section;

b. A certification that the facility meets the siting standards, as applicable, of [9VAC20-121-210](#);

c. A certificate signed by a professional engineer that the facility has been designed and constructed in accordance with the design and construction standards, as applicable, of [9VAC20-121-220](#);

d. Design plans certified by a professional engineer consisting of at least the following:

(1) A title sheet indicating the facility name, who prepared the plans, the person for whom the plans were prepared, a table of contents, and a location map showing the location of the site and area to be served.

(2) An exterior site plan identifying building dimensions of the transfer or treatment facility and the location of property boundaries and building setbacks, fencing, loading or unloading areas, vehicle staging and queuing locations, and parking areas.

(3) An interior site plan identifying location and size of all receiving, storage, temporary storage, including storage areas to be used to segregate unauthorized waste, radioactive waste, hazardous waste, and other untreated waste from treated waste, and processing areas, and location of treatment units, reusable container washing stations, and floor drains.

(4) A process flow diagram for all treatment units showing, piping and instrumentation, vents, and liquid discharge locations;

e. Documentation of the authorization to discharge into an approved sanitary sewer system or publicly or privately owned treatment works;

f. A certification that the facility meets the standards of Part III ([9VAC20-121-100](#) et seq.) and Part IV ([9VAC20-121-200](#) et seq.), as applicable, and a copy of the regulated medical waste management plan to be maintained in the operating record in accordance with [9VAC20-121-330](#). The certification shall also include a statement that the emergency contingency plan has been provided to the local police and fire departments, local emergency manager, and local emergency health coordinator;

g. Alternate treatment technologies shall provide a copy of the treatment technology approval;

h. A treatment plan for each treatment unit in accordance with [9VAC20-121-330 E](#);

i. For treatment facilities, a treated waste disposal plan in accordance with [9VAC20-121-280 D](#) ;

j. A closure plan in accordance with [9VAC20-121-330 G](#);

k. Demonstration of legal control over the site for the permit life;

l. A certification from the State Corporation Commission that the business entity pursuing the permit-by-rule status is a valid entity, authorized to transact its business in Virginia. This requirement does not apply to those facilities owned solely by governmental units;

m. Closure cost estimates and proof of financial responsibility as required by the Financial Assurance Regulations for Solid Waste Disposal, Transfer, and Treatment Facilities ([9VAC20-70](#)). Proof of financial responsibility must be for the entity identified in subdivision A 2 l of this section. For treatment facilities, proof of financial responsibility is required prior to department approval to begin operation in accordance with [9VAC20-121-320](#); and

n. The applicable permit fees under the provisions of [9VAC20-90](#).

3. Public participation.

a. The applicant for a new regulated medical waste transfer station or treatment facility shall publish a notice once a week for two consecutive weeks in a major local newspaper of general circulation of the intent to construct and operate a facility eligible for a permit-by-rule. The notice shall include:

- (1) A statement of the applicant's intent to apply for a permit-by-rule to operate a regulated medical waste transfer station or treatment facility;
- (2) A brief description of the proposed facility and its location;
- (3) A statement that the purpose of the public participation is to identify issues of concern, to facilitate communication and to establish a dialogue between the applicant and persons who may be affected by the facility;
- (4) Announcement of a 30-day comment period, in accordance with subdivision A 3 d of this section;
- (5) Announcement of the date, time, and location for a public meeting to be held in accordance with subdivision A 3 c of this section;
- (6) The name, address, and telephone number of the owner's or operator's representative who can be contacted by interested persons to answer questions or receive comments on the siting and operation of the proposed regulated medical waste facility; and
- (7) Location where copies of the documentation to be submitted to the department in support of the permit-by-rule notification can be viewed and copied in accordance with subdivision A 3 b of this section.

b. The owner or operator shall place a copy of the documentation and support documents in a location accessible to the public in the vicinity of the proposed facility.

c. The owner or operator shall hold a public meeting not earlier than 14 days after the publication of the notice required in subdivision A 3 a of this section and no later than seven days before the close of the 30-day comment period. The meeting shall be held to the extent practicable in the vicinity of the proposed facility at a time convenient for the public.

d. The public shall be provided 30 days to comment on the technical and the regulatory aspects of the proposal. The comment period will begin on the date the owner or operator publishes the first notice in the local newspaper.

e. The requirements of this section do not apply to the owners or operators of a regulated medical waste treatment unit that has received a permit from the department based on the regulations promulgated by the State Air Pollution Control Board or State Water Control Board that required facility-specific public participation procedures.

4. Upon receiving the certifications and other required documents, including the results of the public meeting and the applicant's response to the comments received, the department shall conduct a completeness review and respond within 30 days.

a. If the applicant's submission for a regulated medical waste transfer station is administratively complete, the applicant shall be deemed to operate under permit-by-rule status.

b. If the applicant's submission for a treatment unit is administratively complete, the applicant shall be deemed to operate under permit-by-rule status and granted authorization to initiate validation testing in accordance with an approved validation protocol and [9VAC20-121-320](#). The facility shall not accept regulated medical waste for treatment until the results of validation testing and operating parameters are submitted and approved by the department.

c. If the applicant's submission is administratively incomplete, the department will respond with a letter stating that the facility will not be considered to have a permit-by-rule or initiate the validation protocol until the missing certifications or other required documentation is submitted. At the time of the initial receipt or at a later date, the director may require changes in the documents designed to assure compliance with this chapter. Should such changes not be accomplished by the facility owner or operator, the facility will not be deemed to have a regulated medical waste management facility permit.

5. A permit-by-rule shall not be transferred by the permittee to a new owner or operator. However, when the property transfer takes place without proper closure, the new owner shall notify the department of the sale and fulfill all the requirements contained in subdivision A 2 of this section. Upon presentation of the financial assurance proof required by Financial Assurance Regulations for Solid Waste Disposal, Transfer, and Treatment Facilities ([9VAC20-70](#)) by the new owner, the department will release the former owner from the closure and financial responsibilities and acknowledge existence of the new permit-by-rule in the name of the new owner.

6. The owner or operator of a facility operating under a permit-by-rule may modify its design and operation by furnishing the department a new certificate and applicable permit fees under the provisions of [9VAC20-90](#). For modifications of design, the new certificate shall be prepared by a professional engineer and shall include new documentation required under subdivision A 2 of this section, as applicable, and subdivision A 3 of this section. For modifications to the operations, the owner or operator shall submit to the department a new certificate and documentation required under subdivision A 2 of this section, as applicable. For treatment units, a new treatment plan and revalidation with department approval to begin operation will be required for design and operation changes that include changing the treatment unit type, changing the treatment unit operating parameters, changes in waste stream, and adding a new treatment unit. Whenever modifications in the

design or operation of the facility affect the provisions of the closure plan, the owner or operator shall revise the closure plan and submit to the department a new certificate and documentation required under subdivision A 2 of this section, as applicable. Should there be an increase in the closure costs, the owner or operator shall submit a new proof of financial responsibility as required by [9VAC20-70](#).

7. The director may terminate a regulated medical waste management facility's coverage under a permit-by-rule and require closure of the facility when the director finds that:

- a. As a result of changes in key personnel, the requirements necessary for a permit-by-rule are no longer satisfied;
- b. The applicant has knowingly or willfully misrepresented or failed to disclose a material fact in the disclosure statement or any other report or certification required under this chapter or has knowingly or willfully failed to notify the director of any material change to the information in the disclosure statement;
- c. Any key personnel have been convicted of any of the crimes listed in § [10.1-1409](#) of the Code of Virginia, punishable as felonies under the laws of the Commonwealth or the equivalent under the laws of any other jurisdiction or has been adjudged by an administrative agency or a court of competent jurisdiction to have violated the environmental protection laws of the United States, the Commonwealth, or any other state, and the director determines that such conviction or adjudication is sufficiently probative of the permittee's inability or unwillingness to operate the facility in a lawful manner; or
- d. The operation of the facility is inconsistent with the facility's regulated medical waste management plan or the requirements of Part IV ([9VAC20-121-200](#) et seq.) of this chapter.

B. Notwithstanding any other provision of this chapter, in the event the director finds an imminent and substantial endangerment to human health or the environment, the director may issue a temporary emergency permit to a facility to allow transfer, treatment, or storage of regulated medical waste. Such permits:

1. May be issued to allow:
  - a. Transfer, treatment, or storage of regulated medical waste at a nonpermitted facility;
  - b. Transfer, treatment, or storage of types of regulated medical waste not covered by the permit for a facility with an effective permit;
  - c. Treatment of regulated medical waste by a new or temporary treatment unit or treatment unit or method not covered by the permit for a facility with an effective permit; or
  - d. Temporary transfer, treatment, or storage activities not covered by the permit for a facility with an effective permit.
2. If oral, the emergency permit shall be followed within five calendar days by a written emergency permit.
3. Shall not exceed 90 days in duration.
4. Shall clearly specify:
  - a. The regulated medical wastes to be received;
  - b. The manner and location of their transfer, treatment, storage, or disposal; and
  - c. For emergency treatment units, the treatment plan in accordance with [9VAC20-121-330 E](#).
5. Shall be accompanied by a public notice including:
  - a. Name and address of the office granting the emergency authorization;
  - b. Name and location of the facility so permitted;
  - c. A brief description of the wastes involved;
  - d. A brief description of the action authorized and reasons for authorizing it; and
  - e. Duration of the emergency permit.
6. Shall incorporate, to the extent possible and not inconsistent with the emergency situation, all applicable requirements of this chapter, and shall include the applicable permit fees under the provisions of [9VAC20-90](#).
7. For emergency treatment units, the facility shall not accept regulated medical waste for treatment until the results of validation testing and operating parameters are submitted and approved by the department.

8. Any permit issued under this subsection may be renewed not more than three times if necessary and with appropriate justification. Each such renewal shall be for a period of not more than 90 days.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-320. Effect of the permit.

A. A regulated medical waste treatment facility will be approved to perform its validation protocol following determination of a complete permit-by-rule application in accordance with the procedures outlined in [9VAC20-121-310](#). Before receipt of waste by the facility, the permittee must:

1. Arrange for a department representative to inspect the site to observe at least one validation test run and perform validation testing in accordance with approved protocols.
2. Submit to the department for approval a summary of the validation test results demonstrating the treatment effectiveness and specifying the operating parameters based on the results of all validation test runs. The report shall include the results of all validation test runs.

B. Following approval by the department of the validation results, a regulated medical waste treatment facility may begin receiving and treating regulated medical waste as defined in the permit-by-rule. The facility shall comply with the operating parameters necessary to achieve treatment. A regulated medical waste treatment facility shall not receive or treat regulated medical waste until the department has approved the validation results and operating parameters to be used for the treatment unit.

C. Each facility permitted to accept regulated medical waste requires periodic inspection and review of records and reports. By accepting coverage under a permit-by-rule in accordance with [9VAC20-121-310](#), the owner or operator agree to the specified periodic inspections.

D. Compliance with a valid permit-by-rule and this chapter during its term constitutes compliance for purposes of enforcement with the Virginia Waste Management Act. However, a permit-by-rule may be modified or terminated for cause as set forth in [9VAC20-121-310 A 6](#) and [A 7](#).

E. A permit-by-rule does not convey any property rights or any sort or any exclusive privilege.

F. A permit-by-rule does not authorize any injury to persons or property or invasion of other private rights or any infringement of federal, state, or local law or regulations.

G. A permit-by-rule may be transferred by the permittee to a new owner or operator only if the permit-by-rule has been terminated and reissued or modified to identify the new owner or operator and incorporate such other requirements as may be necessary. Upon presentation of the financial assurance proof required by [9VAC20-70](#) by the new owner, the department will release the old owner from the old owner's closure and financial responsibilities and acknowledge existence of the new or modified permit-by-rule in the name of the new owner.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-330. Regulated medical waste management plan.

A. All permitted regulated medical waste management facilities, such as regulated medical waste transfer stations or treatment facilities, shall prepare and maintain a written regulated medical waste management plan. The plan shall include a certification page signed by a responsible official. This signature shall certify the plan meets the requirements of this chapter. The plan shall be maintained in the operating record and shall be made available for review by the department upon request. The plan shall include, at a minimum, the items in subsections B through G of this section.

B. A written waste acceptance plan, which includes, at a minimum:

1. Types and quantities of regulated medical waste to be managed, including sources of the waste and proposed service areas (if waste is accepted from offsite). The plan shall identify:

a. Acceptable waste types for treatment onsite (if applicable); and

- b. Acceptable wastes types to be transferred to another approved facility for treatment or management offsite. The plan shall include a description of the offsite facility that will receive the waste, including the name, address, and telephone number for the receiving facility and how specific waste types will be managed.
2. Protocols for identification and segregation of regulated medical waste from other types of waste, including radioactive wastes, hazardous wastes, and other solid waste. The plan shall include a description of how incoming waste will be monitored to detect the presence of radioactive materials and actions that will be taken to verify the source of any alarm.
3. Procedures for handling Category A waste in accordance with [9VAC20-121-160](#).
4. Facilities that accept regulated medical waste from offsite shall include the following:
- a. A description of onsite traffic control, schedules, and routing for waste delivery vehicle flow and methods of enforcement of traffic flow plans for the waste delivery vehicles;
- b. Procedures for arrival confirmatory inspections of each delivery vehicle and their loads to ensure that the waste has been packaged and transported in accordance with the U.S. Department of Transportation Hazardous Materials Regulations and this chapter;
- c. A description of how the waste will be off-loaded, weighed, and compared to the shipping paper that accompanies the waste and how any discrepancies will be resolved; and
- d. For each generator or customer, the facility shall maintain a signed certificate, contract, or equivalent document for each load or inclusive of all loads received from the generator in which the generator affirms that the loads do not contain unauthorized waste.
5. Procedures for handling regulated medical waste received from onsite or offsite that is not packaged, labeled, or marked correctly; leaking, dented, ripped, torn, bulging, or otherwise damaged; or not accompanied by a shipping paper.
- C. A written description of the procedures for the detection and management of unauthorized waste in accordance with [9VAC20-121-230 K](#). The plan shall contain, at a minimum:
1. A list of unauthorized waste types that are not acceptable for management at the facility.
2. Methods used by the operator to prevent management of unauthorized wastes, such as routine monitoring and observation of incoming waste, generator agreements, and informational materials.
3. Procedures to detect and address any unauthorized waste discovered at the facility, including the protocol for identifying and contacting the generator and to prevent recurrence.
4. Procedures for containing and storing each type of unauthorized waste, such as radioactive or hazardous waste, until it is removed for proper management, including designated storage locations, storage timeframes, packaging, and labeling.
5. Instructions for documenting and notifying the department of receipt and ultimate disposition of unauthorized waste.
- D. A written operations plan that includes, at a minimum:
1. A general description of the overall process and equipment used. The plan shall include the following: hours of operation; process rate; procedures for daily startup; methods, containers, and other devices for the collection, off-loading, tipping, and conveyance of regulated medical waste from the point of generation or receipt to areas for processing; normal loading, unloading, and waste handling procedures; and timeframes for transfer or treatment.
2. Protocols for packaging and labeling regulated medical waste for treatment onsite or transport offsite, including protocols for labeling or marking wheeled carts, containers, conveyance systems, or other items used for moving regulated medical waste.
3. Procedures for temporary onsite storage of regulated medical waste until it is collected for treatment onsite or transport offsite. The plan shall identify each storage location and capacity, the maximum length of time the waste will be stored, and procedures used to document compliance with required storage timeframes.
4. Methods and equipment used to empty, clean, and disinfect reusable containers in accordance with [9VAC20-121-130](#), including types and quantities of reusable containers and disinfectant to be used, disinfection procedures utilized between uses, and final disposal in case of damage or wear and tear. The plan shall also include a description of appropriate personal protective equipment, such as puncture and leak resistant gloves, safety glasses or face shield, protective coveralls or bib, protective footwear, and mask or respiratory protection as needed, used to protect personnel when cleaning and disinfecting reusable containers.
5. Procedures for spill prevention and response and how spilled waste will be collected, packaged, and the spill area decontaminated in accordance with [9VAC20-121-140](#). This includes locations and contents of all spill containment and cleanup kits.

6. Names, addresses, and telephone number of final treatment or ultimate disposal facilities to be used for untreated waste and treated residues, facility-generated wastes, unauthorized waste, hazardous waste, radioactive waste, and other waste bypassed or disposed.
  7. A description of equipment and procedures used to control access to areas used for the storage, transfer, and treatment of regulated medical waste. The plan shall identify all entry and exit points where access is controlled.
  8. Methods and equipment used for routine cleaning and disinfection of facility equipment, floors, vehicles, and other surfaces that come into contact with regulated medical waste.
  9. Measures used to control and monitor for fire, dust, noise, litter, odors, vectors, and blowing debris at the facility.
  10. Collection and management of effluent, wash water, and other runoff from facility floors, storage and processing areas, waste compactors, and reusable container cleaning and disinfection areas, including location and discharge of drains.
  11. Identification of all appropriate personal protective equipment, such as puncture and leak resistant gloves, safety glasses or face shield, protective coveralls or bib, protective footwear, and mask or respiratory protection as needed, and when the items are used to protect personnel managing regulated medical waste at the facility. The plan shall also include a description of donning and offing procedures for personal protective equipment.
  12. A self-inspection plan that at a minimum includes copies of the inspection checklists that comply with [9VAC20-121-230 U](#) along with a description of the types of potential problems and corrective actions that may result from the inspections.
  13. A schedule and description of initial and annual refresher training to be provided to employees in-person, in a language they can understand, including interactive training, and the types and numbers of adequately trained personnel. Initial training shall be provided within seven working days of employment, and annual refresher training shall be provided within one year from the date of the last training. Training shall include:
    - a. Operational procedures in accordance with [9VAC20-121-230 V](#);
    - b. Protocols to recognize, manage, document, and report unauthorized waste in accordance with [9VAC20-121-230 K](#);
    - c. Procedures for retraining staff when noncompliance or other incidents occur; and
    - d. Any other specialized waste training specific to the job function.
  14. Procedures for recordkeeping in accordance with [9VAC20-121-340](#). The procedures shall address how inventory will be managed and methods used to track, link, and document specific incoming waste loads to specific outgoing waste loads.
  15. A description of the type and estimated daily quantity of any facility-generated waste residues and procedures for handling and disposal of the residues.
- E. A written treatment plan for each unit used to treat regulated medical waste that meets the standards of [9VAC20-121-240](#) and [9VAC20-121-250](#) and includes at a minimum:
1. A detailed description of the treatment technology to be used, including:
    - a. An overview of the treatment process and description of the treatment unit, including manufacturer, model name or number, and treatment capacity;
    - b. Procedures for equipment startup and shut down including warm-up, loading and unloading wastes, and anticipated load size during routine operation;
    - c. A description of built-in automatic controls and fail safe mechanisms to ensure the waste cannot bypass the treatment process;
    - d. If applicable, methods used to grind, shred, or puncture containers or packaging before, during, or after treatment, along with the methods to prevent exposure to the waste; contain any aerosol, bioaerosol, or mists caused by the process; and treat or filter any air evacuated from the chamber during processing;
    - e. If applicable, methods to transfer from a grinder or shredder to or from a treatment unit under forced draft ventilation that removes fumes from the operations area to a safe discharge;
    - f. Methods for maintaining negative pressure atmospheric control in the vessel and filtering all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with efficiency of 99.97% for 0.3 microns. Installation and maintenance of filters shall be specified;
    - g. Methods to manage effluent including location and discharge of drains; and

- h. A description of preventative maintenance that is performed on the treatment unit, including on engineering and electronic controls.
2. Identification of acceptable waste types to be treated and a listing of types of wastes that shall not be treated.
3. Treatment unit operating parameters (e.g., cycle duration, temperature, pressure, chemical concentration, irradiation exposure time, or other treatment parameters as applicable) and a description of how the operating parameters will be monitored and recorded, including number, type, and location of parametric monitoring devices, thermochemical indicators, and thermochemical recording devices, as applicable for routine operation.
4. Identification of the biological indicators to be used and documentation that lack of growth in the treated indicator corresponds to a 6 Log<sub>10</sub> reduction of viable spores. An explanation of why each indicator is suitable for the treatment process and wastes to be treated, including referencing any standards, guidelines, or information from peer reviewed journals, shall be included. The facility shall also specify the:
  - a. Type of biological indicators (spore strip, suspension, or self-contained), including a copy of the supplier's certificate of performance (or certificate of analysis) that identifies the organism (genus, species, strain, and population), purity, and for thermal treatment systems (including autoclaves) the D-value, and Z-value;
  - b. Estimated shelf life and storage conditions to be maintained;
  - c. Culture medium, incubation procedures, and incubation time (for self-contained biological indicators) and the media, growth, and culture conditions (for non-self-contained biological indicators), including how the results are to be interpreted and recorded;
  - d. Carrier system or material and primary packaging;
  - e. Relative resistance to temperature, pressure, chemicals, irradiation, infectious agents, or any other conditions used in the treatment process; and
  - f. Number, location, and placement of untreated (control) and treated indicators relative to the coldest spot in the treatment unit as identified by the manufacturer.
5. Number, type, and placement of thermochemical indicators, including a description of how results will be interpreted and recorded.
6. A validation plan that includes a detailed description of the validation testing protocol used to demonstrate effective treatment by each treatment unit that meets the standards of [9VAC20-121-260](#) and includes:
  - a. Surrogate waste load composition, including packaging type, porosity, relative percentages of inorganic and organic components, moisture content, thermal resistance, and a relative breakdown of solid components, such as blood culture bottles, plastics (including suction canisters), microbiological waste, and sharps;
  - b. Load configuration including packing density, orientation, and load size;
  - c. Number, type, and location or placement of biological indicators; thermochemical indicators; thermochemical recording devices; and any other methods used to monitor operating parameters and accuracy of parametric monitoring devices during validation runs to ensure that the gauge or electronic read-out is a true reflection of conditions inside the treatment unit;
  - d. A description of how the results will be interpreted and documented; and
  - e. Identification of who will conduct the validation testing.
7. A detailed description of the periodic challenge testing procedures used to evaluate the effectiveness of each treatment device under full loading, which meets the standards of [9VAC20-121-270](#) and includes:
  - a. Frequency of challenge testing to be performed;
  - b. Number, type, and location or placement of biological and thermochemical indicators, and other methods used to monitor operating parameters;
  - c. A description of how the results will be interpreted and documented;
  - d. Procedures used to address challenge test failures, including evaluating and correcting any issues with the treatment cycle and unit, and management of untreated regulated medical waste to include temporary storage or diversion to another approved facility for treatment or disposal; and
  - e. Procedures for reporting failing results of challenge testing to the department in accordance with [9VAC20-121-340](#).
8. Identification of all appropriate personal protective equipment, such as puncture and leak resistant gloves, safety glasses or face shield, protective coveralls or bib, protective footwear, and mask or respiratory protection as needed, and when the items are used to protect

personnel.

9. Safety procedures used to minimize occupational exposure and prevent physical injury to operators during loading, unloading, and treatment cycle.

10. Procedures for handling and disposing of treated wastes, including packaging, labeling, and transport.

11. A copy of the treated waste disposal plan in accordance with [9VAC20-121-280 D](#).

F. A written emergency contingency plan that describes the organized, planned, coordinated courses of action to be followed in the event of emergencies and nonoperation. In addition to submission to the department, the plan shall be provided to the local police and fire departments, local emergency manager, and local emergency health coordinator. The plan shall include:

1. Procedures to minimize hazards to human health and the environment from utility failure, fires or explosions, spills, leaks and releases, and exposure to regulated medical waste.

2. A description of the actions facility personnel shall take in the event of various emergency situations (fire, explosion, catastrophic loss, temporary shutdown, release of regulated medical waste or regulated medical waste constituents, or other incident that could threaten human health or the environment), including evacuation procedures.

3. A list of available fire protection and emergency equipment, and appropriate uses, such as fire extinguishers, emergency safety showers, eye wash stations, spill control materials, and alarm systems.

4. Procedures to be employed in the event of equipment breakdown or maintenance events, including standby equipment, extension of operating hours, or diversion of waste to another facility.

5. A list of onsite and offsite backup equipment with names and telephone numbers where offsite equipment may be obtained.

6. Provisions for loading, unloading, storage, transfer, treatment, or other disposal capabilities to be used during emergency situations, including when the facility downtime exceeds 24 hours.

7. The designation of alternate treatment areas or plans for transfer of stored waste in the event facility or system downtime exceeds 72 hours.

8. Procedures for spill cleanup and decontamination following a release of regulated medical waste.

9. A description of arrangements made with the local police and fire department that allow for immediate entry into the facility by their authorized representatives should the need arise, such as in the case of response personnel responding to an emergency situation.

10. The telephone numbers for local fire and police departments.

11. An identification of personnel designated as emergency coordinators. A list of names, addresses, and phone numbers (office and home) of all persons qualified to act as an emergency coordinator for the facility. Where more than one person is listed, one shall be named as primary emergency coordinator and the other shall be listed in the order in which they will assume responsibility as alternates. The emergency coordinator must be onsite or on-call and is responsible for responding to emergencies and coordinating emergency response measures.

12. A description of where and how emergency response information will be posted.

G. A written closure plan that identifies the steps necessary to completely close the facility or unit at its full operation under the permit conditions, which includes:

1. Procedures for removal of regulated medical waste, treated residue, and other materials for proper treatment or disposal;

2. Methods for cleaning and disinfecting the unit or facility and all related equipment, structures, and surfaces;

3. A description of any sampling to be conducted to ensure the facility has been decontaminated;

4. A schedule for final closure including, as a minimum, the anticipated date when wastes will no longer be received, the date when completion of final closure is anticipated, and intervening milestone dates that will allow tracking of the progress of closure; and

5. Actions necessary for facility abandonment or uses other than for regulated medical waste management.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-340. Recordkeeping and reporting required of a permittee.

A. Regulated medical waste management facilities having coverage under a permit-by-rule shall maintain and retain records and reports as required by this chapter.

B. A facility shall retain records whenever monitoring is required.

1. The facility shall retain records of all monitoring information, including all calibration and maintenance records and all original recordings for continuous monitoring instrumentation, for at least three years from the sample or measurement date. The director may request that this period be extended.

2. Records of monitoring information shall include:

- a. The date, exact place, and time of sampling or measurements;
- b. The name of the individuals who performed the sampling or measurements;
- c. The date analysis were performed;
- d. The name of the individuals who performed the analysis;
- e. The analytical techniques or methods used; and
- f. The results of such analyses.

C. The facility must maintain accurate written or digital records as required by this chapter. Records shall include all records required by the facility permit, this chapter, or other applicable regulations. Records must be maintained at the facility or another location approved by the department for at least three years from the date of the record, sample or measurement date, treatment date, shipping date, or receipt date. The department may request that this period be extended. Records shall be available for review by the department as requested.

D. The facility shall maintain a regulated medical waste management plan in the operating record in accordance with [9VAC20-121-330](#).

E. The owner or operator of a regulated medical waste management facility under a permit-by-rule that transfers or treats regulated medical waste, except for a captive regulated medical waste management facility, shall submit a Solid Waste Information and Assessment report to the department by March 31 of each year in accordance with [9VAC20-81-80](#).

F. A disclosure statement identifying all key personnel as required by § [10.1-1408.1](#) of the Code of Virginia shall be on file with the department and updated on a quarterly basis as necessary. At least one operator listed as key personnel on the facility's disclosure statement shall be licensed by the Board for Waste Management Facility Operators as required by § [10.1-1408.2](#) of the Code of Virginia.

G. If regulated medical waste is received from offsite, records shall be maintained for three years following receipt of the waste and shall include the date of receipt, name of each offsite generator, transporter, type and quantity (weight or volume) of waste received, and dates of subsequent treatment onsite or shipment offsite. The facility shall maintain a signed certificate, contract, or equivalent document for each load or inclusive of all loads received from offsite in which the generator affirms that the load does not contain hazardous waste or radioactive materials, unless the facility is permitted to receive those types of wastes.

H. If regulated medical waste is shipped or transferred offsite, the facility shall maintain records, including copies of all shipping papers, specifying the date of shipment, type, and quantity (weight or volume) of waste removed from the site and the names, addresses, and telephone numbers of both the transporters and the destination facility receiving the shipments for treatment or disposal.

I. A regulated medical waste treatment facility shall maintain an onsite treatment log at each treatment unit that is complete for the preceding three-year period. The log shall record the date, start time, end time, and operator of each treatment cycle; the type and quantity (weight or volume) of regulated medical waste treated onsite; monitoring records for the operating parameters (e.g. time, temperature, pressure, and chemical concentration) achieved throughout each treatment cycle; and the results of all validation and periodic challenge testing. Monitoring records shall include original recordings for continuous monitoring instrumentation and parametric controls as well as the results of all biological and thermochemical indicators. Where multiple treatment units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location as long as the records distinguish which treatment unit is applicable to each record. The consolidated logs shall be retained for three years and be available for review.

J. The facility shall retain records of all unauthorized waste in accordance with [9VAC20-121-230](#) K.

K. The facility must maintain a record of self-inspections in an inspection log. The log must include the date and time of the inspection, the name of the inspector, a description of the inspection, including the identity of the specific equipment and structures inspected, observations recorded, and the date and nature of any remedial actions implemented or repairs made.

L. Written documentation of all training received by each employee, including the date and topics of the training, shall be maintained in the facility's operating record.

M. A regulated medical waste management facility shall be subject to the following reporting requirements. The facility shall report to the department any noncompliance, emergency, or unusual condition that may endanger health, the environment, or the facility's operation. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within five working days of the time the facility becomes aware of the circumstances. The written report shall contain a description of the circumstances and its cause; the period of occurrence, including exact dates and times; and if the circumstance has not been corrected, the anticipated time it is expected to continue. It shall also contain steps taken or planned to reduce, eliminate, and prevent reoccurrence of the circumstances resulting in an unusual condition or noncompliance, to include retraining of staff as necessary. Reportable conditions include:

1. Any interruption to operations that requires implementation of the facility's emergency contingency plan or diversion of regulated medical waste to another management facility;
2. Releases or discharges of regulated medical waste from a fire, explosion, storm, or other emergency that could endanger human health or the environment outside the facility;
3. Unauthorized discharge of effluent, wash water, waste, or other pollutant to surface water (i.e., offsite, natural water body or tributary, including wetlands);
4. Spills of regulated medical waste in any areas not protected from the elements, such as outside of a building;
5. Storage of regulated medical waste beyond capacity or storage timeframes;
6. Failing results of periodic challenge testing;
7. Receipt or discovery of unauthorized waste;
8. Receipt of Category A waste; and
9. Shipment of regulated medical waste offsite in inappropriate packaging.

N. Copies of all reports required and records of all data used to complete the permit-by-rule application must be retained for at least three years from the date of the report or application. The director may request that this period be extended.

O. When the permittee becomes aware that the permittee failed to submit any relevant facts or submitted incorrect information in a permit-by-rule application or in any report to the department, the permittee shall promptly submit such omitted facts or the correct information with an explanation.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

#### Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

#### Part VI

##### Variance Application Procedures

##### 9VAC20-121-400. General.

A. Any person affected by this chapter may apply to the department for a variance from any requirement of this chapter. Variance determinations shall be subject to the provisions of the Virginia Administrative Process Act (§ [2.2-4000](#) et seq. of the Code of Virginia).

B. The department shall not accept any variance application relating to:

1. Equivalent testing or analytical methods contained in EPA Publication SW-846;
2. A change in the regulatory requirements that the applicant is currently violating until such time as the violation has been resolved through the enforcement process.

#### Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

9VAC20-121-410. Variance to requirements.

A. The director may grant a variance from any regulation contained in Part III ([9VAC20-121](#)-100 et seq.) through Part V ([9VAC20-121](#)-300 et seq.) of this chapter to an applicant if the applicant demonstrates to the satisfaction of the director that:

1. a. Strict application of the regulation to the facility will result in undue hardship that is caused by the applicant's particular situation;
- b. The alternate is equally protective of human health and the environment as that provided for in the regulations; or
- c. Technical conditions exist that make a strict application of the regulation difficult to achieve; and
2. Granting the variance will not result in an unreasonable risk to the public health or the environment.

B. Effects of the decisions.

1. When the director renders a decision under this section in accordance with the procedures contained in [9VAC20-121](#)-420, the director may:

- a. Deny the application;
- b. Grant the variance as requested; or
- c. Grant a modified or partial variance.

2. When a variance is granted, the director may:

- a. Specify the termination date of the variance; or
- b. Include a schedule for:
  - (1) Compliance, including increments of progress, by the facility with each requirement of the variance; and
  - (2) Implementation by the facility of such control measures as the director finds necessary in order that the variance may be granted.

## Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

## Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023; Errata, 39:15 VA.R. 2075 March 13, 2023.

9VAC20-121-420. Administrative procedures.

A. Persons requesting variance from a provision of this chapter shall submit an application for such variance in accordance with this section.

1. All applications submitted to the director shall include:
  - a. The applicant's name and address;
  - b. A statement of applicant's interest in the proposed action;
  - c. A description of the desired action and a citation to the regulation from which a variance is requested;
  - d. A description of the need and justification for the proposed action;
  - e. The duration of the variance, if applicable;
  - f. The potential impact of the variance on public health or the environment;
  - g. Other information believed by the applicant to be pertinent; and
  - h. The following statements signed by the applicant or his authorized representative:

"I certify that I have personally examined and am familiar with the information submitted in this application and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information

is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

2. In addition to the general information required of all applicants under this part:

- a. To be successful the applicant shall address the applicable standards and criteria;
- b. An explanation of the applicant's particular situation that prevents the facility from achieving compliance with the cited regulation; and
- c. Other information as may be required by the department.

B. The variance application shall be processed in accordance with this subsection.

1. After receiving an application that includes the information required in subsection A of this section, the director will determine whether the information received is sufficient to render the decision. If the information is deemed to be insufficient, the director will request that additional information be furnished.

2. The applicant may submit the additional information requested or may demonstrate that the additional information should not be required. If the director agrees that the additional information should not be required, the director will act in accordance with subdivision 3 of this subsection.

3. After the application is deemed complete:

- a. The director will make a tentative decision to grant or deny the variance request.
- b. If the variance request is tentatively denied, the director will offer the applicant the opportunity to withdraw the request, submit additional information, or proceed with the evaluation.
- c. The director will issue a notice tentatively granting the variance request. Notification of this tentative decision will be provided by newspaper advertisement in the locality where the applicant is located. The director will accept comment on the tentative decision for 30 days.
- d. After evaluating all public comments, the director will, within 15 days after the expiration of the comment period:
  - (1) Notify the applicant of the final decision; and
  - (2) Notify all persons who commented on the tentative decision.

C. Decision resolution.

1. In the case of a denial, the applicant has a right to request a formal hearing to challenge the rejection.
2. If the director grants a variance request, the notice to the applicant shall provide that the variance may be terminated upon a finding by the director that the applicant has failed to comply with any variance requirements.

Statutory Authority

§ [10.1-1402](#) of the Code of Virginia; 42 USC § 6941 et seq.; 40 CFR Part 257.

Historical Notes

Derived from Virginia Register [Volume 39, Issue 13](#), eff. March 15, 2023.

Forms (9VAC20-121)

[Solid Waste Management Facility Permit Applicant's Disclosure Statement \(Cover Sheet\), DEQ Form DISC 01 \(rev. 9/2020\)](#)

[Solid Waste Management Facility Permit Applicant's Disclosure Statement - Key Personnel Statement, DEQ Form DISC 02 \(rev. 9/2020\)](#)

[Local Government Certification Request, DEQ Form CERT 01 \(rev. 8/2018\)](#)

[Regulated Medical Waste Management Facility Permit by Rule Form, DEQ Form RMW PBR \(rev. 3/2023\)](#)

[Application for Evaluation and Approval of Regulated Medical Waste Treatment Technology, DEQ Form RMWTP 01 \(rev. 8/2024\)](#)

Documents Incorporated by Reference (9VAC20-121)

[Managing Solid Waste Contaminated with a Category A Infectious Substance \(April 2024\), approved for publication by the National Security Council-led Countering Biological Threats Interagency Policy Committee on March 13, 2024.](#)

Website addresses provided in the Virginia Administrative Code to documents incorporated by reference are for the reader's convenience only, may not necessarily be active or current, and should not be relied upon. To ensure the information incorporated by reference is accurate, the reader is encouraged to use the source document described in the regulation.

As a service to the public, the Virginia Administrative Code is provided online by the Virginia General Assembly. We are unable to answer legal questions or respond to requests for legal advice, including application of law to specific fact. To understand and protect your legal rights, you should consult an attorney.